



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 202

[Docket No. FDA-2009-N-0582]

RIN 0910-AG27

Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend its regulations concerning direct-to-consumer (DTC) advertisements (ads) for human prescription drugs presented in television or radio format and stating the name of the drug and its conditions of use (DTC TV/radio ads). Specifically, the final rule implements a requirement of the Federal Food, Drug, and Cosmetic Act (FD&C Act), added by the Food and Drug Administration Amendments Act of 2007 (FDAAA), that in such DTC TV/radio ads, the major statement relating to side effects and contraindications must be presented in a clear, conspicuous, and neutral manner. As directed by FDAAA, FDA is establishing standards to determine whether the major statement in DTC TV/radio ads is presented in a clear, conspicuous, and neutral manner.

DATES: This rule is effective [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The compliance date of this rule is [INSERT DATE 365 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading

of this final rule into the “Search” box and follow the prompts, and/or go to the Dockets

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I. Executive Summary

A. Purpose of the Final Rule

This final rule implements a statutory requirement that in human prescription drug advertisements presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use (DTC TV/radio ads), the major statement relating to side effects and contraindications (major statement) (Ref. 1) must be presented in a clear, conspicuous, and neutral manner. (As used in this document, unless specifically stated otherwise, references to DTC ads and similar terms encompass ads for human prescription drugs only.) In enacting that requirement, Congress directed FDA to issue regulations establishing standards for determining whether a major statement is presented in a clear, conspicuous, and neutral manner. The final rule establishes five standards that, independently and collectively, help ensure that the major statement is presented in a clear, conspicuous, and neutral manner. This rule does not change the content of the major statement.

This rule is an incremental addition to a longstanding body of prescription drug advertising regulations. The statute and regulations regarding DTC ads have long required that, with limited regulatory exceptions, prescription drug ads include information about the advertised drug's risks as well as its effectiveness. This final rule complements the longstanding requirements for including risk information in prescription drug ads, setting standards for the manner of presentation of the major statement of side effects and contraindications in DTC TV/radio ads to help ensure that this risk information is presented effectively--that is, in a way that helps consumers notice, attend to, and understand the drug's risks.

By helping consumers notice, attend to, and understand a drug's risks, the final rule directly advances two substantial Government interests. First, the measures required by the final rule help ensure that DTC TV/radio ads convey a truthful and non-misleading net impression about the advertised drug, including its risks. Second, these measures help ensure that

consumers are better informed when they participate in healthcare decision making. Although prescription drugs must be prescribed by a healthcare provider (HCP) and cannot be accessed by consumers directly, consumers make decisions that have a critical effect on health and well-being, such as whether to fill a prescription, whether to initiate taking the prescribed drug, and whether to continue taking the drug in adherence to a prescribed regimen. The clear, conspicuous, and neutral presentation of risk information in DTC TV/radio ads, in addition to benefit information, helps ensure that these ads convey a truthful and non-misleading net impression about the advertised drug and that consumers are better informed when they participate in healthcare decision making.

B. Summary of the Major Provisions of the Final Rule

This final rule specifies five standards that, independently and collectively, help ensure that the major statement is presented in a clear, conspicuous, and neutral manner. The final rule establishes that the information must be presented in consumer-friendly language and terminology that is readily understandable. The audio information in the major statement must be at least as understandable as the audio information presented in the rest of the ad. In ads in TV format, the information presented in the audio portion of the major statement must also be presented concurrently in text for a sufficient duration to allow it to be read easily. In ads in TV format, the information in text must be formatted such that the information can be read easily. The ad must not include audio or visual elements during the presentation of the major statement that are likely to interfere with comprehension of the major statement.

C. Legal Authority

This final rule amends FDA's prescription drug advertising regulations to be consistent with the current requirements of the FD&C Act, as amended by FDAAA, that in human prescription drug ads presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner. In addition,

FDAAA directed FDA to establish standards for determining whether the major statement in DTC TV/radio ads is presented in a clear, conspicuous, and neutral manner--and does so in this rule. Furthermore, this rule is authorized by various provisions of the FD&C Act.

D. Costs and Benefits

The benefits of this final rule stem from and include helping consumers notice, attend to, and understand the major statement in DTC TV/radio ads. The standards in the final rule help to ensure that DTC TV/radio ads convey a truthful and non-misleading net impression about the advertised drug and help ensure that consumers are better informed when they participate in healthcare decision making. We discuss the benefits qualitatively.

The costs of this final rule include the cost to read and understand the rule, to revise a firm's¹ standard operating procedures, and to revise TV and radio ads during the transition period leading up to the compliance date. We also expect there to be modest ongoing costs for industry to review future DTC TV/radio ads to ensure that these advertisements comply with this final rule and an ongoing opportunity cost related to a potential change in the relative allocation of time within the ad between the presentation of the major statement and the presentation of other content. The total present value of costs over a 10-year time horizon ranges from \$104.8 million to \$331.8 million, with a primary estimate of \$218.3 million, at a 7 percent discount rate; the present value ranges from \$123.8 million to \$393.0 million, with a primary estimate of \$258.4 million, at a 3 percent discount rate. Annualized costs over a 10-year time horizon range from \$14.9 million to \$47.2 million, with a primary estimate of \$31.1 million, at a 7 percent discount rate; annualized costs over a 10-year time horizon range from \$14.5 million to \$46.1 million, with a primary estimate of \$30.3 million, at a 3 percent discount rate.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/Acronym	What It Means
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research

¹ In this document, “firm” refers to manufacturers, packers, and distributors of prescription drugs and all of their representatives, including both individuals and corporate entities.

CFR	Code of Federal Regulations
CMP	Civil Monetary Penalties
DTC	Direct-to-Consumer
FDA	United States Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FD&C Act	Federal Food, Drug, and Cosmetic Act
FR	Federal Register
FTC	Federal Trade Commission
HCP	Healthcare provider, healthcare professional, healthcare practitioner
OMB	Office of Management and Budget
SUPERs	Superimposed text
TV	Television
U.S.C.	United States Code

III. Background

A. Overview of Direct-to-Consumer Prescription Drug Advertising and Its Regulation

American consumers encounter ads for an enormous variety of goods and services, each ad seeking to attract their attention, pique their interest, and ultimately drive demand for the advertised product or service. But few ads provide information about products as important as prescription drugs. Prescription drugs are integral to healthcare, and decisions about their use can have critical effects on health and well-being. These decisions about prescription drug use not only impact each individual patient's health and well-being but also affect others, including family, friends, and caregivers.

Of course, by definition, prescription drugs cannot be accessed directly by consumers; they must be prescribed by a practitioner licensed by law to administer such drugs (commonly referred to as a healthcare professional, provider, or practitioner, here referred to as HCPs). But the billions of dollars drug manufacturers spend annually to promote their prescription drugs directly to consumers through TV ads and other media demonstrate recognition that consumers make critical choices related to treatment with prescription drugs. For example, consumers decide whether to make an initial appointment with an HCP, whether to ask the HCP about a particular drug, whether to fill a prescription, whether to take the drug, and whether to continue taking it in adherence to the prescribed regimen.

These decisions are informed by what consumers know about a drug, starting with the most basic awareness of the drug's availability and the health condition(s) for which it is approved. For U.S. consumers, that knowledge is often derived from DTC ads, a major source of information about human prescription drugs (Refs. 2 to 6). Analysis of submissions by firms to FDA's Center for Drug Evaluation and Research (CDER) of ads that the firms identify as DTC radio or TV ads, together with spending data, illustrates the widespread use of these formats for prescription drug advertising. For example, in 2007, when the clear, conspicuous, and neutral manner requirement was enacted, firms identified 74 new DTC radio ads in submissions to FDA's CDER, spending \$30 million on all prescription drug DTC radio ads in that year (Ref. 7). In 2020, firms identified 56 new DTC radio ads in submissions to FDA's CDER, while spending on all prescription drug DTC radio ads increased to \$57.4 million for that same year (Ref. 8).

TV ads for prescription drugs are even more prevalent, and attract enormous absolute and relative spending. In 2007, firms identified 434 new DTC TV ads in submissions to FDA's CDER, and the reported expenditure for all prescription drug DTC TV ads in that year was \$2.87 billion of a total of \$4.77 billion spent on DTC advertising (Ref. 7). In 2020, firms identified 564 new DTC TV ads in submissions to FDA's CDER, and the reported expenditure for all prescription drug DTC TV ads that year was \$4.58 billion of a total of \$6.58 billion spent on DTC advertising (Ref. 9). While the number of TV ads has increased, a published analysis of DTC TV ads found that ads in 2016 presented many of the same elements (e.g., use of emotional appeals, focus on drug benefits over health information) as ads in a 2004 analysis, indicating a general consistency in such ads over time (Ref. 10).

Prescription drug firms have long maintained that their DTC ads respond to consumer desire for information about prescription drugs (Ref. 11). However, in light of their pervasiveness, consumers are likely to be exposed to DTC TV/radio ads even if they are not actively seeking information about any prescription drug.

Evidence shows that DTC ads inform important consumer decisions about healthcare. For example, surveys indicate that DTC advertising influences whether consumers seek more information about a drug, decide to visit and discuss an advertised drug with an HCP, or decide not to see an HCP (Refs. 12 to 17). This is one reason why Congress enacted the requirement in section 502(n) of the FD&C Act addressed by this final rule, requiring the major statement of side effects and contraindications in DTC TV/radio ads to be presented in a clear, conspicuous, and neutral manner. As one lead sponsor explained during Senate floor consideration, a motivation for the legislation was “[r]esearch...show[ing] that people are more likely to go to the doctor, ask thoughtful questions, and discuss sensitive health issues with their doctors as a result of DTC ads.” See 153 Cong. Rec. S5631 (May 7, 2007) (statement of Sen. Roberts).

Like all advertisers, prescription drug firms have ample business incentives to present their products in a positive light to potential consumers. But those business incentives do not assure clear communication of the advertised drug’s negative attributes to consumers. Firms’ lack of business incentives, combined with DTC ads’ ability to inform and influence consumer participation in healthcare decision making, points to the need for Government regulation of prescription drug ads in particular. Ensuring that DTC ads that provide benefit information about prescription drugs also effectively communicate risk information is particularly important because the effective presentation of risk information is critical to helping to ensure that DTC TV/radio ads convey a truthful and non-misleading net impression about the advertised drug, including its risks, and that consumers are better informed when they participate in healthcare decision making, as described elsewhere in this document. Further, the consumer is uniquely positioned to know about particular, personal circumstances or limitations (e.g., other medicines and supplements being taken, constraints on time or other resources, allergies, preferences) that are important factors in decision making about prescription drug treatments. See Ref. 18 noting the changing role of consumer as processor of health information. When taking into account their own specific circumstances and what they know about a prescription drug, a consumer

decides whether they will accept undesirable side effects in light of health benefits, whether they will devote the necessary ongoing attention to monitoring and management to optimize net outcomes, or even whether they need to avoid or prefer to avoid a drug completely because the risks for that individual are too great. As further explained below, the measures in this rule join other longstanding requirements that help remedy the lack of business incentive for prescription drug firms to effectively communicate the risks of their products to consumers, and thus, the standards established in this rule, independently and collectively, advance the substantial Government interests in helping to ensure that DTC TV/radio ads convey a truthful and non-misleading net impression about the advertised drug and that consumers are better-informed when they participate in healthcare decision making.

1. Government Interests in This Regulation

For DTC TV/radio ads, the measures in this rule enhance the manner of presentation of risk information to increase the likelihood that consumers will notice, attend to, and understand the major statement in these ads, which conveys the drug's major side effects and contraindications. Improving consumer understanding of these risks helps ensure that an ad conveys a truthful and non-misleading net impression about the advertised drug. And improving consumer understanding also helps ensure that consumers are better-informed when they participate in healthcare decision making.

As the Supreme Court has recognized, "there is no question that [the Government's] interest in ensuring the accuracy of commercial information in the marketplace is substantial" (*Edenfield v. Fane*, 507 U.S. 761, 769 (1993)). Consistent with this overall interest for all advertising, this rule helps ensure that DTC TV/radio ads communicate risk so that they convey a truthful and non-misleading net impression about the advertised drug. This purpose was also identified by an author of the statutory provision underlying this regulation. See 153 Cong. Rec. S5631 (May 7, 2007) (statement of Sen. Roberts during floor consideration) ("My amendment requires that major statements about a drug's side effects, contraindications, and effectiveness in

television or radio ads be presented in a clear and conspicuous manner so as not to mislead the public.”). In addition, although Federal law does not prohibit DTC advertising of any legally marketed drug, research indicates that some consumers erroneously believe that drugs that have serious side effects cannot be advertised to consumers (Ref. 19). While this rule does not change the content of the major statement in prescription drug ads, presenting the major statement in a clear, conspicuous, and neutral manner will help consumers understand if there are serious risks associated with a drug. Thus, this rule seeks to help ensure that DTC ads communicate risk information in a manner that helps consumers notice, attend to, and understand the drug’s risks.

The Government also has a substantial interest in promoting consumer understanding of a prescription drug’s risks in order to help ensure that consumers are better informed when they participate in healthcare decision making at each of the many important healthcare decision points already described, taking account of their individual circumstances. See, e.g., *American Hosp. Ass’n v. Azar*, 983 F.3d 528, 538 (D.C. Cir. 2020) (“providing consumers with factual price information to facilitate more informed health care decisions”); *CTIA - The Wireless Ass’n v. City of Berkeley*, 928 F.3d 832, 846 (9th Cir. 2019) (informing consumers regarding radiation emissions from cell phone and methods of avoiding excessive exposure); *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 567 (6th Cir. 2012) (“effectively communicat[ing] the associated health risks [of tobacco products] so that consumers possess accurate, factual information when deciding whether to buy tobacco products”); *Nat’l Elec. Mfrs. Ass’n v. Sorrell*, 272 F.3d 104, 115 (2d Cir. 2001) (“increasing consumer awareness of the presence of mercury in a variety of products”).

Ensuring that a drug’s specific risks are effectively communicated in DTC TV/radio ads helps inform consumers--another purpose identified by an author of the legislation underlying this rulemaking. See 153 Cong. Rec. S5645 (May 7, 2007) (statement of Sen. Harkin) (stating that the amendment seeks “to help the FDA and the companies to provide better information so that consumers can make real choices”). This regulation, by helping to assure that ads that

address a prescription drug's benefits also facilitate understanding of risks, helps consumers when they are exploring healthcare options.

Improving consumer understanding of an advertised prescription drug's risks to better inform those consumers when they participate in healthcare decision making is especially important in the American healthcare environment. Evidence indicates that HCPs have limited time with patients (Refs. 20 to 23) and discussions with patients are only one among varied HCP duties that may include clinical care, research, mentoring, teaching, electronic health recordkeeping, and other administrative duties (Refs. 24 and 25). Moreover, as previously noted, consumers have information about their individual circumstances that may be relevant, or even critical, to any decision about use of a particular prescription drug. Helping ensure consumers have the information they need to formulate appropriate questions or bring up relevant information about their personal circumstances during interactions with HCPs helps consumers make productive use of those interactions.

2. Consistency With Longstanding Statutory and Regulatory Measures Regarding Prescription Drug Risk Presentation

The basic concepts of the rule continue the approach taken in many longstanding measures applicable to prescription drug advertising and labeling. For example, since 1938 (for labeling) and 1976 (for advertising), section 201(n) of the FD&C Act has reflected the principle that disclosing material facts that include the "consequences" of using the drug to which labeling or advertising relates is key to ensuring that such communications are not misleading.

Moreover, the more precise principle that when drug manufacturers choose to advertise prescription drugs, those ads must provide risk information was recognized with the 1962 enactment of section 502(n) of the FD&C Act, specifying that prescription drug ads must include "a true statement of...other information in brief summary relating to side effects, contraindications and effectiveness as shall be required in regulations" Accordingly, a specific regulatory requirement to convey a prescription drug's risks in its advertising has been

in place since 1963. See 28 FR 6375 at 6376 (June 20, 1963). And since 1969, the prescription drug advertising regulations have specifically addressed the use of a statement of the advertised drug's major side effects and contraindications in TV and radio advertising. See 34 FR 7802 (May 16, 1969). Similarly, many drug firms have also long acknowledged that DTC ads that convey benefit information should also contain risk information (Ref. 11).

After industry's initial forays into DTC prescription drug advertising in the early 1980s, FDA confirmed that DTC advertising was likewise subject to these established prescription drug advertising regulations. See 50 FR 36677 at 36678 (September 9, 1985) and § 202.1(e)(1) (1985). This was the regulatory framework that was in place in 2007, when Congress amended the underlying statutory provision in section 502(n) of the FD&C Act to codify the importance of ads effectively communicating risk to consumers by further specifying that this "major statement relating to side effects and contraindications" in human prescription drug advertisements presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, be presented in a clear, conspicuous, and neutral manner.

The specific "clear, conspicuous, and neutral manner" provision that this regulation addresses is also part of a longstanding line of statutory and regulatory provisions that help ensure that an inadequate manner of presentation does not undermine required disclosures about prescription drugs. See, e.g., 21 U.S.C. 352(c) (enacted by Pub. L. 75-717 (June 25, 1938)), establishing misbranding if prominence, conspicuousness, and terms used to present required elements of labeling for drugs and devices are not sufficient to "render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." In fact, provisions for presenting required information clearly and prominently have been a part of requirements for prescription drug advertising since the first such regulations were issued. See 28 FR 6375 at 6377 (initial regulations issued under section 502(n) of the FD&C Act, including 21 CFR 1.105(i), requiring information concerning side effects and contraindications to appear "in reasonably close association with the information concerning effectiveness" with "the same

relative degree of prominence as the information concerning effectiveness, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.”); see also current § 202.1(e)(7)(viii).

This rulemaking complements these longstanding prescription drug advertising requirements. This rule brings additional clarity to existing provisions about the major statement in DTC TV/radio ads by providing information on how that major statement must sound and (in the case of TV ads) look.

In sum, this rulemaking is an important incremental measure, adding to a longstanding body of legal requirements addressing effective communication of risk information about prescription drugs in consumer-directed promotional communications. The rule helps ensure that DTC TV/radio ads convey a truthful and non-misleading net impression about the advertised drug and helps ensure that consumers are better informed when they participate in healthcare decision making.

B. History of the Rulemaking

In the proposed rule (*Federal Register* of March 29, 2010 (75 FR 15376)), we proposed to amend our regulations regarding DTC TV/radio ads in accordance with section 901(d)(3) of FDAAA (see 21 U.S.C. 352(n)). Specifically, we proposed to implement provisions of FDAAA requiring that in human prescription drug advertisements presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner.

We proposed the following four standards for determining whether the major statement in these ads is presented in the statutorily required manner:

- #1. Information is presented in language that is readily understandable by consumers.
- #2. Audio information is understandable in terms of the volume, articulation, and pacing used.

- #3. Textual information is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily.
- #4. The advertisement does not include distracting representations (including statements, text, images, or sounds or any combination thereof) that detract from the communication of the major statement.

We also solicited comment on a potential fifth standard to require that in TV ads, the major statement be presented simultaneously in both audio and visual portions of the ad--a practice known as dual modality.

In developing these proposed standards, FDA considered standards developed by other Federal Agencies, including the Federal Trade Commission (FTC), the Department of the Treasury, the Commodity Futures Trading Commission, and the Securities and Exchange Commission, for determining whether disclosures in TV/radio ads, as well as disclosures in other contexts, are “clear and conspicuous” (75 FR 15376 at 15377-15379). Then, as now, the Agency considered these standards to be highly relevant because they aim to ensure that required disclosures are effectively presented so that consumers are not misled about the attributes of the product or service that is the subject of the communication. As discussed in section III.A.1 of this document, FDA has a similar interest in ensuring that DTC TV/radio ads convey a truthful, non-misleading net impression about the advertised drug.

FDA noted in the preamble of the proposed rule that these other Federal standards revealed the widespread incorporation of common themes, which FDA in turn incorporated in its own proposed standards, and now incorporates in its final standards, because they are all factors that contribute to whether the audience will notice, attend to, and understand the risk information in the major statement (75 FR 15376 at 15378-15379). These themes were: “ease of comprehension of the language used in the disclosure; the formatting and location of textual information in the disclosure; audio considerations such as pacing, volume, and qualities of

speech; and the presence of any distracting elements during the disclosure” (75 FR 15376 at 15378). The language of the standards from other Federal Agencies cited in the proposed rule and the themes incorporated by those other Federal standards remain unchanged.²

In the proposed rule, FDA also noted that its proposed standards were consistent with factors described and discussed in its draft guidance entitled “Presenting Risk Information in Prescription Drug and Medical Device Promotion” (May 2009) (draft Risk Guidance; Ref. 26) (available at <https://www.fda.gov/media/76269/download>) (75 FR 15376 at 15379). That draft guidance reflects consideration of a broad body of social science research into human cognition and factors that impact attention and comprehension.

The Agency also noted in the proposed rule that it was unaware of any previous standards or regulations concerning the definition of “neutral manner” in the context of required disclosures but considered “neutral manner” to mean “unbiased manner” of presentation and thus proposed standards accordingly. The Agency suggested, “To achieve a ‘neutral,’ unbiased presentation of the major statement and to avoid undercutting its effectiveness, the major statement must not be presented in competition with other elements if these elements would arrest the attention and distract consumers from the presentation of the risk information” (75 FR 15376 at 15380). As part of the overall establishment of standards for effectively communicating necessary risk information in a clear, conspicuous, and neutral way, we requested comments on standards to establish what is “neutral” (75 FR 15376 at 15380).

In the proposed rule (75 FR 15376 at 15379), we noted that FDA had conducted a study on the impact of certain types of visual distraction on consumer understanding of risk and benefit information in DTC TV ads for prescription drugs (referred to in this document as the Distraction Study), the results of which were at that time still undergoing analysis (and, consequently, were not the basis of any specific provision in the proposed rule). FDA

² The definition of “clear and conspicuous” in one regulation cited in the proposed rule, 12 CFR 40.3, is now part of 12 CFR 1016.3.

acknowledged the limitations of this study, but because FDA believed it could be relevant to the rulemaking, announced plans to place the report of the results into the docket for the proposed rule with opportunity for comment. Accordingly, in the *Federal Register* of January 27, 2012 (77 FR 4273), we announced the addition of the Distraction Study report to the docket (Ref. 27), and we reopened the rulemaking comment period until February 27, 2012, to provide an opportunity for interested parties to comment on the study as it relates to the proposed standards (Docket No. FDA-2009-N-0582). In the *Federal Register* of March 29, 2012 (77 FR 16973), we reopened the comment period for the rulemaking proceeding again until April 9, 2012, in response to a request for more time to submit comments to the Agency on the Distraction Study report as it related to the proposed standards.

The Distraction Study examined three factors that might influence viewers' understanding of the risk information presented in the audio portion of a TV ad. This research evaluated the effects of:

- Presence or absence of superimposed text (SUPERs) that concurrently presented verbatim, key words and phrases from the audio presentation of risk;
- Variations in the positive (affective) tone of visual images; and
- Visual information that was either inconsistent or consistent with the audio risk information.

The results of the Distraction Study indicate that presenting the same risk information visually (i.e., in SUPERs) and in audio at the same time (dual modality) improves consumers' understanding of the risk information. The Distraction Study did not find support for the hypotheses that understanding of the risk information is adversely influenced by concurrently presenting positively toned visual images or by concurrently presenting information in visuals that is inconsistent with the risk information presented in audio (Ref. 27). While the Distraction Study and its results were a consideration during the formulation of the standards in this final

rule, they were neither the sole justification for, nor the only information considered in, the development of any of the proposed or final standards.

FDA based the standards in the proposed rule on scientific research, literature, and existing Government standards, all of which continue to be relevant for the final rule. Research findings supporting the proposed rule's standards--including research findings on dual modality and distraction--were available during the public comment periods and have been subsequently corroborated by additional research, including research supporting that comprehension and recall is increased when information is provided in both audio and text and also when information is presented without distraction. In this final rule, the fundamental concepts remain the same as those articulated in the proposed rule. Evolving technologies have allowed for DTC TV/radio ads to be presented on a broader range of devices and disseminated via a broader range of platforms since the issuance of the proposed rule.³ However, from an informal review of ads firms recently submitted to FDA in accordance with regulatory requirements (21 CFR 314.81(b)(3)(i) and 601.12(f)(4)), FDA observes that firms have not developed distinct ads for dissemination on these new devices and platforms and that DTC TV/radio ads remain essentially the same. Moreover, fundamental attributes of communication that impact the likelihood that audiences will notice, attend to, and comprehend information, which the standards in the proposed and final rules concentrate on, do not turn on the delivery technology.

We recognize the passage of time between the closure of the last comment period on the proposed rule and the issuance of this final rule, which resulted in large part from competing demands for limited Agency resources, such as repeated redirection of personnel into emergency operations for natural disasters, the opioid epidemic, and infectious disease outbreaks including

³ See, e.g., Ipsos, "Half of American TV viewers watch 10 or more hours of TV during the week," Report, July 28, 2021, available at <https://www.ipsos.com/en-us/news-polls/american-tv-viewing-habits-2021>, accessed September 7, 2023; Leiner, D.J. and N.L. Neuendorf, "Does Streaming TV Change Our Concept of Television?" *Journal of Broadcasting & Electronic Media*, 66(1):153-175, 2022. doi:10.1080/08838151.2021.2013221; Radioworld, "How Technology Helps Radio and Its Listeners," April 9, 2019, available at <https://www.radioworld.com/columns-and-views/guest-commentaries/rab-audio-technology-helps-radio>, accessed September 7, 2023.

Ebola, Zika, and the COVID-19 pandemic. Despite this passage of time, FDA concludes that this rulemaking is both procedurally and substantively sound. A central purpose of notice-and-comment rulemaking is to obtain public input, see *Make the Rd. N.Y. v. Wolf*, 962 F.3d 612, 634 (D.C. Cir. 2020) and *United States v. Cain*, 583 F.3d 408, 420 (6th Cir. 2009). The Agency has provided three public comment periods, offering meaningful opportunities for any interested persons to comment on the rulemaking and the bases for the standards laid out in this rulemaking.⁴ Indeed, no parties have requested additional opportunity for comment since closure of the last comment period, even though the Agency’s plans to issue a final rule have been consistently made public through the Unified Agenda since 2017. Moreover, as noted above, the Agency has determined that there are no material changes in the fundamental concepts, relevant facts (including evolving technologies), scientific research, literature, or existing Government standards underlying the rule. For these reasons, FDA concludes that it is appropriate to issue this final rule without offering a fourth opportunity for public comment.

C. Summary of Comments to the Proposed Rule

There were three public comment periods for the proposed rule. In total, FDA received over 70 submissions from consumers, public interest or consumer groups, trade and industry associations, healthcare providers, and drug firms. Overall, the majority of comments express support for the proposed rule. Several comments request that FDA edit the proposed rule, provide clarification, or provide more detail. Several comments suggest that FDA undertake additional research before finalizing the rule. We address these and other comments throughout this document.

D. General Overview of Final Rule and Changes to the Proposed Rule

⁴ See also *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2385, (2020) (The Administrative Procedure Act (APA) prescribes the “maximum procedural requirements that an agency must follow in order to promulgate a rule.”) (internal quotation marks omitted); *Sanofi-Aventis US LLC v. HHS*, 58 F.4th 696, 706 (3d Cir. 2023) (“all the APA requires of an agency before publishing a final rule is (1) putting a notice of proposed rulemaking in the Federal Register, (2) accepting comments on that proposal, and (3) considering those comments. See 5 U.S.C. § 553(b)-(c).”)

This final rule implements a FDAAA requirement (codified in 21 U.S.C. 352(n)) that in human prescription drug advertisements presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner. This statutory requirement has been in effect since March 25, 2008. In line with other Government standards, findings from scientific research and literature, and the proposed rule, this final rule establishes standards for determining whether the major statement in these ads is presented in a clear, conspicuous, and neutral manner.

We discuss the following:

- In the final rule, we do not address “neutral” separately from the overall concept of a “clear, conspicuous, and neutral manner” of presentation, nor do we associate that attribute exclusively with any single standard. Rather, we conclude that the final standards, independently and collectively, contribute to a clear, conspicuous, and neutral manner of presentation.
- Proposed standard #1 (final standard #1; § 202.1(e)(1)(ii)(A)): “Information is presented in language that is readily understandable by consumers.” The final standard specifies that the major statement must be presented in consumer-friendly language and terminology that is readily understandable.
- Proposed standard #2 (final standard #2; § 202.1(e)(1)(ii)(B)): “Audio information is understandable in terms of the volume, articulation, and pacing used.” The final rule clarifies that the audio information in the major statement must be at least as understandable as the audio information presented in the rest of the ad in terms of the volume, articulation, and pacing used.
- Proposed potential standard #5 (final standard #3; § 202.1(e)(1)(ii)(C)): The final rule includes a standard requiring that for ads in TV format, the major statement be presented concurrently using both audio and text (dual modality). To achieve dual modality: (1)

either the text displays the verbatim key terms or phrases from the corresponding audio, or the text displays a verbatim complete transcript of the corresponding audio; and (2) the text is displayed for a sufficient duration to allow it to be read easily. For the purposes of this standard, the duration is considered sufficient if the text display begins at the same time and ends at approximately the same time as the corresponding audio.

- Proposed standard #3 (final standard #4; § 202.1(e)(1)(ii)(D)): “Textual information is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily.” The final rule removes the duration requirement from this standard, including it instead in final standard #3, and clarifies that this standard applies to the text portion of the major statement in ads in television format. For clarity, we also reorganized the phrasing of this standard.
- Proposed standard #4 (final standard #5; § 202.1(e)(1)(ii)(E)): “The advertisement does not include distracting elements (including statements, text, images, or sounds or any combination thereof) that detract from the communication of the major statement.” The final rule revises the standard to specify that, in order to satisfy it, during presentation of the major statement, the ad does not include audio or visual elements, alone or in combination, that are likely to interfere with comprehension of the major statement.

We also made the following non-substantive editorial changes on our own initiative:

- Section 202.1: Relocated text that defines prescription drug for purposes of this section (previously included in § 202.1(e)(1)). Within this definition, replaced the phrase “drugs for use by man” with the phrase “drugs intended for use by humans.”
- Section 202.1(e): Divided information into subordinate paragraphs for clarity, ease of reading, and plain language.

- Section 202.1(e)(1)(i): Added subparagraphs for ease of reading and reference to § 202.1(e)(1)(ii)(C) for clarity. Replaced “approved or permitted package labeling” with “approved or permitted product labeling.”
- Section 202.1(e)(1)(ii): Revised introductory language to reflect that it is the manner of presentation of the major statement that is “clear, conspicuous, and neutral,” if the standards that follow are met.

IV. Legal Authority

This final rule amends § 202.1 to be consistent with the current requirements of section 502(n) of the FD&C Act, as amended by section 901(d)(3) of FDAAA, which establishes a requirement that in human prescription drug ads presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner. In addition, FDA was directed by FDAAA (see section 901(d)(3)(B)) to establish standards for determining whether the major statement in DTC TV/radio ads is presented in a clear, conspicuous, and neutral manner--and does so in this rule. Furthermore, this rule is authorized by various statutory provisions, including sections 201, 301, 502, 505, 512, and 701 of the FD&C Act.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

During the initial comment period (March 29 to June 28, 2010), FDA received more than 30 submissions on the proposed rule from consumers, public interest groups, trade associations, and the drug industry. When we reopened the comment period to allow for comment on the Distraction Study report as it relates to the proposed standards (January 27 to February 27, 2012, and March 29 to April 9, 2012), we received nearly 40 additional submissions.

In sections V.B through V.O of this document, we describe the comments received on the proposed rule and provide our responses. To make it easier to identify the comments and our

responses, the word “Comment,” in parentheses, appears before the comment’s description, and the word “Response,” in parentheses, appears before our response. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number and, in some cases, we have separated different subjects discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment’s value or importance or the order in which comments were received. We reviewed all comments and carefully considered all points and perspectives. However, comments not directly relevant to this rulemaking were read and considered but are not discussed in this document.

B. General Comments

The majority of comments, including input from industry, support the proposed rule, while only a few comments oppose the rule. Several comments indicate that the proposed rule was an important first step, but even more needs to be done, and some suggest that FDA needs additional information or research results before the regulation is finalized. Various other comments request clarification on certain issues in the proposed rule. We address these and other comments throughout this document.

C. Research Studies--Comments and FDA Response

In the proposed rule, FDA referenced a number of research studies relevant to the proposed standards generally and to dual modality specifically, and also referenced the Agency’s draft Risk Guidance, which itself describes a well-established body of social science research relevant to the standards in the proposed and final rule. As previously described, FDA also mentioned the Distraction Study in the proposed rule, although its results were still undergoing analysis at that time, and indicated that FDA intended to add the study report to the docket for the rulemaking when available and provide opportunity for public comment, as FDA believed those study results might provide helpful information to consider in the rulemaking. FDA

subsequently provided two opportunities for the public to comment on the results and FDA's analyses of the study and how it related to the proposed standards (77 FR 4273 and 77 FR 16973). Many of the comments discuss how the Distraction Study relates to the proposed standards. Several comments conclude that the results of the study directly support the proposed rule. However, several other comments argue that the study design was flawed or did not support the proposed rule. Several comments suggest that additional research should be conducted regarding distraction and the understanding of risk information by consumers.

Comments on the results of the Distraction Study as it relates to proposed standard #4 regarding distracting elements that detract from the communication of the major statement are addressed in section V.J of this document (final standard #5).

Comments pertaining to the use of dual modality in the Distraction Study are addressed in section V.K of this document.

However, we briefly address several general comments related to the Distraction Study and other research here.

(Comment 1) Several comments suggest that the Distraction Study did not examine a sufficient number of factors regarding consumers' understanding of risk information. One comment notes that the Distraction Study did not examine all four proposed standards to determine what would be considered clear, conspicuous, and neutral. Another comment points out that there are many factors beyond those studied that affect the assessment of risk. This comment suggests that FDA should examine how individual perception of risk is influenced by personal experiences, education level, race, gender, age, and knowledge of the agent creating the risk.

Another comment states that the Distraction Study failed to address the full context in which the benefits and risks of prescription drugs are actually considered, specifically with respect to the doctor-patient relationship. The comment argues that doctor-patient interaction is an integral part of the communication of benefits and risks for prescription drugs and thus must

be considered in any assessment regarding risk communication. The comment suggests additional studies be conducted, including: (1) studies that measure the effect of DTC ads on the quality of any subsequent discussions between the patient and physician and (2) studies that measure comprehension of benefits and risks only after consultation with a physician.

One comment suggests that FDA should consider additional research to determine the elements of advertising that may distract a viewer's attention from the major statement. Another comment notes that no study can account for all possible distractions consumers might face.

(Response 1) Many of these comments appear to overstate the role of the Distraction Study with regard to the development of the standards for a clear, conspicuous, and neutral presentation of the major statement. We conclude that there is a strong basis for the final rule without the Distraction Study or the additional research that some comments suggest be conducted.

The Distraction Study was designed only to examine the effects of three particular, pre-defined factors: the presence or absence of SUPERS that concurrently presented verbatim, key words and phrases from the audio presentation of risk; variations in the positive (affective) tone of visual images; and visual information that was either inconsistent or consistent with the audio risk information. Consistent with the limitations of the Distraction Study, which FDA acknowledged in the proposed rule (see 75 FR 15376 at 15379), neither the proposed nor final standards for "clear, conspicuous, and neutral manner" of presentation of the major statement are contingent on its results.

Indeed, a much larger body of social science research, together with disclosure standards of other Federal agencies and ordinary experience with situations where multiple factors compete for attention and may affect comprehension, informs the proposed and final standards for a clear, conspicuous, and neutral manner of presentation of the major statement. For example, the Agency's draft Risk Guidance, referenced in the proposed rule as describing factors consistent with the proposed rule's standards (75 FR 15376 at 15379), included cognitive science research

that predated the Agency's Distraction Study and demonstrated that, while there is some variation based on expertise, all people have limits on the amount of information they can think through and process at one time (see draft Risk Guidance, at p. 6 and fn. 20 (in this rule, Refs. 28-30)). Further, the draft guidance notes that to process information, a person must first pay attention to it. The guidance then goes on to discuss multiple factors (with underlying research) that contribute to whether people will pay attention to information, including formatting factors. Among other things, the draft guidance points to the well-established body of research that existed at the time of the proposed rule--and has been further corroborated since that time--that various elements can interfere with attention and comprehension. See, e.g., draft guidance p. 18, fn. 47 (in this rule, Refs. 31-33); p. 19, fns. 54 to 56 (in this rule, Refs. 34-36); and p. 20, fn. 61 (in this rule, Ref. 37). References cited in the Distraction Study report that was added to the docket for this rulemaking and made available for public comment include additional research on well-documented distracting effects of certain other elements. (See Distraction Study report, p. 3, fn. 1, citing research on scene changes (in this rule, Ref. 38) and music (in this rule, Ref. 39).) Similar information about social science research relevant to other aspects of proposed standards #1 through #4 also appears in the draft Risk Guidance, which the proposed rule itself references. The public had the opportunity to comment on the rule and the Agency's use of the guidance and research to inform the proposed standards. That research remains relevant to this final rule. The proposed and final standards also have a basis in disclosure standards of other Federal agencies (cited in the proposed rule and unchanged since) and ordinary experience with situations where multiple factors compete for attention and may affect comprehension. As to dual modality, the proposed rule summarized a substantial body of research supportive of the utility of this technique, predating the Distraction Study (75 FR 15376 at 15383). As discussed in section V.K of this document, findings of this research regarding the positive impact of dual modality have been corroborated subsequently by the Distraction Study and other research.

Other comments submitted to the docket for the final rule discuss technical details of the Distraction Study's methodology and analyses, rather than the standards in the rule. Sections V.J and V.K of this document address non-technical comments related to the Distraction Study's methodology as it relates to final standard #3 (section V.J) and final standard #5 (section V.K). However, because the Distraction Study was only one of many pieces of information FDA considered when formulating the standards for this rule, technical comments on the study methodology are not further discussed here.

(Comment 2) One comment recommends that FDA develop strategies to ensure consumer understanding of the information contained in DTC ads, such as using patient focus groups to pre-approve the most common risk statements. Additionally, the comment suggests that other elements, such as font size, color, and placement, should be tested with consumers. The comment further suggests that FDA should conduct research to provide an evidence-based assessment of the proposed standards to ensure that they result in consumer-directed ads that effectively communicate risk in a clear, conspicuous, and neutral way. The comment concludes that this research would allow FDA to use quantitative, documented evidence, rather than relying on the consensus of expert opinion.

Two comments also suggest that FDA should consider conducting research and a further analysis on how individual elements combined and presented together would affect the overall communication of the advertised drug's potential benefits and associated risks. A separate comment suggests that the communication of benefits and risks in DTC ads should be tested on an ad-to-ad basis against quantitative standards for evaluating comprehension and understanding among the intended audience.

(Response 2) As part of the rulemaking process culminating in the standards in this final rule, FDA considered many resources, including the many comments submitted during the multiple comment periods, and the literature, research, and other Government standards described elsewhere in this document. In light of the consistency of findings in the research

evaluating the presentation of risk information in DTC ads for prescription drugs from the time of the proposed rule through now, as well as the other Federal Government standards for clear and conspicuous disclosures of information cited in the proposed rule and still in place today, we conclude that we have sufficient information to finalize this regulation without additional research.

D. The Major Statement--Comments and FDA Response

In proposed § 202.1(e)(1)(i), FDA proposed to add the term “major statement” in parentheses after the phrase “major side effects and contraindications” to reflect the Agency’s interpretation that this is the meaning of the terminology used in section 502(n) of the FD&C Act as amended, an interpretation consistent with previous usage (see 75 FR 15376 and 15379; Ref. 1). We did not receive comments directly on this proposal and our final rule includes this provision for the same reasons we proposed it. We did receive comments and questions about the major statement in general.

(Comment 3) One comment suggests that FDA should incorporate the concept of “net impression” (the message communicated by all elements of the piece as a whole) by adding the following language to the end of proposed § 202.1(e)(1)(i): “The adequacy of the major statement will be determined not just in relation to risk-related statements, but by the net impression of the advertisement as a whole.”

(Response 3) We disagree with adding the suggested language. Although both the major statement and other components of the ad collectively contribute to the overall net impression, under section 502(n) of the FD&C Act, the requirement that certain information be presented in a “clear, conspicuous, and neutral manner” applies specifically to “the major statement relating to side effects and contraindications”--not to the ad as a whole. Because this requirement is specific to the presentation of the major statement, a failure to satisfy this requirement cannot be remedied by the presentation of statements in other portions of the ad. For this reason, we decline to add the proposed language, which would allow for the interpretation that an

inadequately presented major statement can be made adequate by statements in other parts of the ad.

FDA will, however, continue to evaluate the net impression created by a DTC TV/radio ad in determining whether that ad is false or misleading. FDA considers net impression as well as evaluates specific risk-related statements in these ads. It is consistent with this approach to issue regulations that recognize the need for the major statement to satisfy, on its own, specific statutory requirements. Furthermore, presenting the major statement in a clear, conspicuous, and neutral manner should help ensure DTC TV/radio ads convey a truthful and non-misleading net impression about the advertised drug.

(Comment 4) One comment recommends that the rule specify the location of the major statement in the ad. This comment suggests that the major statement should not appear in the middle of the ad “where it can be bookended by benefit information and is least likely to be retained by consumers.”

(Response 4) We decline to include in the final rule a provision specifying exactly where the major statement must appear in the ad. This final rule’s standards for presenting the major statement in a clear, conspicuous, and neutral manner complement, rather than displace, FDA’s longstanding approach to assessing whether the ad as a whole complies with other requirements. To ensure that the ad provides fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug, and to assess whether it conveys a truthful and non-misleading net impression about the advertised drug, FDA already considers the placement of risk information together with many other elements of the piece, including framing, signaling, themes, and other risk presentation factors.

E. Standards to Determine a Clear, Conspicuous, and Neutral Manner--General Comments and

FDA Response

In this final rule, as directed by FDAAA, FDA establishes standards for determining whether the major statement in DTC TV/radio ads is presented in a clear, conspicuous, and

neutral manner as required by section 502(n) of the FD&C Act. (Of five final standards, two apply only to ads in television format.)

Although we believe that the five standards established by this rule, when applied collectively, will best help ensure that the major statement in a DTC TV/radio ad is presented in a clear, conspicuous, and neutral manner, each standard independently enhances the manner of presentation to increase the likelihood that consumers will notice, attend to, and understand the advertised drug's major side effects and contraindications. In the event of a stay or invalidation of any standard(s), those that remain in effect would continue to function sensibly⁵ to advance these statutory objectives and provide useful standards for firms to meet their existing statutory obligation. For example, invalidation of a standard that addresses visual aspects of presentation would have no effect on standards addressing audio aspects or terminology. Likewise, in the absence of final standard #3 (dual modality) or final standard #5 (audio or visual elements that are likely to interfere with comprehension), each of the other standards would continue to contribute to a clear, conspicuous, and neutral manner of presentation of the major statement. Therefore, it is FDA's intent to preserve each of the rule's standards to the fullest possible extent, to help advance the important Government interests described in section III.A.1.

As noted in section III.B of this document, in the proposed rule, FDA stated that it was unaware of any previous standards or regulations concerning the definition of "neutral manner" in the context of required disclosures and requested comment on this topic. In addition, in conjunction with proposed standard #4, FDA stated, "To achieve a 'neutral,' unbiased presentation of the major statement and to avoid undercutting its effectiveness, the major statement must not be presented in competition with other elements if these elements would arrest the attention and distract consumers from the presentation of the risk information" (75 FR

⁵ See, e.g., *Belmont Mun. Light Dep't v. FERC*, 38 F.4th 173, 188 (D.C. Cir. 2022) (finding severability of a portion of an administrative action, applying the principle that severability is appropriate where "the agency prefers severability to overturning the entire regulation" and where the remainder of the regulation "could function sensibly without the stricken provision") (citations omitted).

15376 at 15380). However, FDA did not intend to suggest that the “neutral” element of the statutory requirement is only explained by or only relates to proposed standard #4, nor did we intend to foreclose the possibility that the other standards contribute to achieving a manner of presentation that is neutral as well as clear and conspicuous. We received comments suggesting ways in which “a neutral manner” could be explained through the other standards. To the extent that comments discuss neutrality specifically with respect to any of the five final standards, we discuss the comments within the sections that address those standards.

(Comment 5) One comment supports the maintenance of a neutral tone in DTC ads to ensure that consumers are able to glean as much information about risk as possible. One comment asks FDA to confirm that “neutral” relates to the way in which the ad presents the major statement as opposed to the substantive content of the major statement. Another comment suggests that neutrality means that the major statement should only include FDA-approved uses and some measure of the risks of potential side effects.

One comment argues that neutrality has nothing to do with distraction and suggests that Congress intended to incorporate a different meaning of neutrality because it had the opportunity to require that the major statement be totally devoid of all potentially distracting information by mandating that it be in plain black-and-white or “tombstone” format. This comment also notes that the definition of “neutral” from Black’s Law Dictionary is “indifferent; unbiased; impartial; not engaged on either side; not taking an active part with either of the contending sides.” The comment states that a DTC ad in TV/radio format is qualitatively neutral if it neither under-warns consumers about the major risks nor overly deters consumers from using a beneficial product. Thus, the comment concludes that neutral should relate to the content or substance of an ad and not the style or manner in which the content is presented.

Furthermore, within a discussion about neutrality, the same comment notes that a DTC TV/radio ad that overemphasizes risks is potentially as misleading as one that overemphasizes benefits. Several other comments express similar views. One of these comments states that how

consumers feel about prescription medications and the impressions they have regarding the safety of these products can affect appropriate use of the products. The comment also notes that the company's research suggests that adherence to a prescribed medication is based on three factors: (1) concerns about the drug (i.e., short- and long-term risks), (2) perceived need for the drug, and (3) concerns about drug cost. Another comment encourages FDA to further consider issuing standards to clarify what could be a subjective concept open to issues of interpretation and meaning. This comment encourages FDA to evaluate through research with target audiences whether an ad is balanced in the presentation of benefits and risks and whether serious risk information in ads is understood.

Another comment suggests that a broad definition of "neutral" should be adopted. The comment proposes that to present information "neutrally" DTC advertisements should compare the advertised product's risks with the expected benefits (including considerations relating to consumer convenience, comfort, cost, and expected benefits); compare the safety and efficacy of the advertised product with other products for the same indication (e.g., existing products both under patent and generic); and compare the safety and efficacy of the advertised product with non-pharmaceutical approaches for the same indication (e.g., lifestyle modifications). This comment claims that including this information will result in a more neutral presentation by giving consumers a balanced picture of the benefits and risks of the advertised product. A separate comment expresses its support of these views.

In response to those comments, another comment says that FDA should not reconstruct the substantive contours of the major statement requirement in the guise of defining neutrality, for example, by requiring such concepts as comparative safety and effectiveness versus other pharmacologic and non-pharmacologic approaches to treatment, including lifestyle modifications.

(Response 5) We agree with the general principle that it is in the interest of the public health that the risk information in an ad is presented in an engaging manner and is neither

overstated nor understated. However, several of these comments focused in some way on a perceived requirement that neutrality apply to DTC TV/radio ads generally and were mistaken as to what information is required to be included in the major statement or thought that FDA might change the content of the major statement through this rulemaking. DTC TV/radio ads, like all prescription drug ads, are required to contain a fair balance of risk and benefit information (§ 202.1(e)(5)(ii)). However, the requirement of a clear, conspicuous, and neutral manner of presentation, as laid out in the statute, relates to the manner of presentation of the major statement and not to the manner of presentation of the ad as a whole. Further, FDA is not using this rulemaking and the requirement of a “clear, conspicuous, and neutral manner” of presentation to change the content of the major statement (e.g., the risk information provided). Thus, this rulemaking, which addresses the manner of presentation of the major statement, does not require that the major statement include benefit information in comparison to risks, quantitative information, or information about other pharmacologic or non-pharmacologic approaches for the same indications.

FDA agrees that neutral means unbiased, and to provide more specific direction to firms, we establish final standards that, independently and collectively, help to ensure that the major statement is presented in a neutral, as well as clear and conspicuous manner. We acknowledge the research cited by the comment that describes how patients’ beliefs about prescription drugs relate to patient propensity to adhere to certain prescription drugs. We agree that consumers’ beliefs and understanding about a prescription drug informs their participation in important healthcare decision making, including decisions about whether to take the prescription drug. This rule, by establishing standards for the clear, conspicuous, and neutral presentation of the major statement in DTC TV/radio ads, helps ensure that consumers are better informed when they participate in healthcare decision making and helps ensure that DTC TV/radio ads convey a truthful, non-misleading net impression about the advertised drug.

(Comment 6) One comment makes two suggestions to overcome what it described as biases held by manufacturers and consumers. First, it asks that the rule require inclusion of the statement that “The FDA has not approved this ad” to correct misleading beliefs that FDA approves all ads and that only drugs that are proven to be very safe can be advertised on TV. This comment argues that this required disclosure would make the major statement more neutral by disassociating the ad from any Government imprimatur regarding the safety of the drug or whether such safety is adequately described by the ad the consumer is seeing. Second, it asks that the rule require that the MedWatch hotline statement be included in DTC TV/radio ads to communicate that, overall, the drug being advertised is not known to be risk-free.

(Response 6) FDA has decided that we will not require through this rulemaking the additional language requested by this comment addressing FDA non-approval of the ad and the MedWatch hotline. As explained more fully throughout this document, this rulemaking does not change the content of the major statement, but rather establishes standards that address the statutory requirement that the major statement be presented in a clear, conspicuous, and neutral manner.

(Comment 7) Another comment states that the Distraction Study did not provide helpful information for FDA to consider in determining whether a major statement is presented in a neutral manner or provide evidence that a neutral presentation of the major statement is essential for the consumer to fully understand the risk and benefit information.

(Response 7) The results of the Distraction Study are not the sole justification for any part of this rule; rather, the results of that study constitute one of many pieces of information FDA considered when formulating the final standards for this rule. Furthermore, to the extent the comment suggests that it may be unnecessary to present the major statement in a “neutral” manner, we note that Congress has established the requirement that the major statement be presented in a “clear, conspicuous, and neutral” manner, and this rule is being issued consistent with that statutory requirement (21 U.S.C. 352(n)).

F. Consumer/Audience--Comments and FDA Response

The clear, conspicuous, and neutral statutory requirement applies to ads for human prescription drugs that state the name of the drug and its conditions of use that are presented directly to consumers in TV or radio format (21 U.S.C. 352(n)). So, this final regulation applies to such ads directed toward consumers. FDA proposed in standard #1 that to be considered clear, conspicuous, and neutral, the major statement must be “presented in language that is readily understandable by consumers.” In the final rule, the language of “by consumers” is not included within this standard, for reasons explained below.

(Comment 8) One comment suggests that FDA add the word “reasonable” before “consumer” in proposed standard #1 to be consistent with FDA’s draft Risk Guidance. A second comment suggests adding more substance to the standard by requiring the firm to take into account its audience either by adding “reasonable consumer” or “consumer[s] to who[m] the ad is directed” to the end of proposed standard #1. Another comment, citing *Sims v. GC Services, L.P.*, 445 F.3d 959, 963 (7th Cir. 2006), suggests that FDA use the standard that the FTC adopted in relation to debt collection practices, i.e., a “least sophisticated consumer” standard--someone who is “uninformed, naïve, or trusting” but who has a “rudimentary knowledge [about the subject] and who is capable of making logical deduction[s] and inferences.”

(Response 8) Because this regulation applies only to DTC TV/radio ads, it is inherent that the audience for these ads is consumers, and it is unnecessary to specify a consumer audience in the codified text of individual standards. Accordingly, although the proposed regulatory text for standard #1 included the words, “by consumers”, we do not include “by consumers” in the text of standard #1 as finalized. It is FDA’s position that the “consumer” audience for a DTC TV/radio ad is an ordinary consumer and that the ordinary consumer acts reasonably--a position that is consistent with the Agency’s longstanding approach in evaluating DTC prescription drug advertising, including the approach reflected in the 2009 draft Risk Guidance (Ref. 26), an approach which remains unchanged since the proposed rule. For the purposes of this

rulemaking, FDA declines to adopt the “least sophisticated consumer” standard used by FTC for debt collection practices, which primarily focuses on specific content related to such practices. The ordinary consumer better aligns with FDA’s interests in addressing the presentation of risk in DTC ads.

G. Proposed Standard #1 (Final Standard #1) (Language)--Comments and FDA Response

FDA proposed in standard #1 (proposed § 202.1(e)(1)(ii)(A)) that to be considered clear, conspicuous, and neutral, the major statement must be “presented in language that is readily understandable by consumers.” The concept of using language tailored to the consumer audience is consistent with other approaches for consumer disclosures (Refs. 40 and 26) (75 FR 15376 at 15378). We retain this concept in the final rule but, as further explained in this section, we modified this standard (final standard #1) to require that the major statement “is presented in consumer-friendly language and terminology that is readily understandable.” We have made these changes in response to comments we received.

(Comment 9) Several comments suggest that the terminology of the major statement, as well as the language used, should be readily understandable by consumers. Some comments say that the risk language in DTC ads is often cumbersome, confusing, and difficult for most consumers to understand. One comment says that most people will not really listen to this information, and a different comment says that ambiguous terms are problematic. One comment also notes that using scientific language in ads may mislead consumers by creating a false impression that the drug has been more rigorously tested and is thus safer than has actually been shown. Another comment requests that the proposed standards mimic FTC phone ad requirements, which require that the disclosure of risk information use the same language (e.g., Spanish) as the presentation of benefit or other parts of the ad.

(Response 9) We generally agree with these comments--both the language and terminology used in the major statement should be readily understandable by consumers. We note that there seemed to be some confusion regarding the meaning of the word “language” in

the proposed rule. FDA did not intend to focus on foreign language requirements through this rulemaking. To help clarify our intent, we added “consumer-friendly” and “terminology” to this standard. These revisions are intended to clarify that the major statement must use consumer-friendly language and terminology that is readily understandable, rather than medical or technical jargon or terms usually more familiar to HCPs.

(Comment 10) One comment states that the neutrality requirement should mean that the risks and benefits presented in DTC ads in TV/radio format are presented at a uniform literacy level with minimum technical jargon and that the information is relayed in a uniform typeface and uniform speed of speaking to minimize the under-comprehension of risks and the distortion of benefits.

Several comments request that FDA define specific criteria for assessing whether the major statement is “readily understandable by consumers,” such as in terms of a standard acceptable reading level. The comments suggest a variety of standards: (1) the Flesch-Kincaid Grade Level readability score; (2) the Agency for Healthcare Research and Quality’s Effective Health Care Program guides, which are written at a sixth-grade literacy level; (3) the least informed person of limited literacy likely to view and be influenced by an ad; or (4) a general sixth-grade reading level.

(Response 10) FDA agrees that final standard #1 is part of the evaluation of whether a major statement is presented in a neutral (as well as clear and conspicuous) manner. As discussed above, the regulation requires consumer-friendly language and terminology that is readily understandable. However, FDA declines to limit this standard through this rulemaking to language associated with a particular grade level of reading or similar criterion as it may be necessary to include certain terms (e.g., reference a disease like “tuberculosis”) in the major statement that could result in a relatively high grade level rating. This final standard requires that the language used to provide the major statement’s risk information is understandable to the ordinary consumer while providing manufacturers with flexibility in designing their ads.

(Comment 11) Several comments seem to respond to our suggestion in the proposed rule that vague terms subject to more than one interpretation should be avoided (e.g., say “more than half” rather than “some patients”) (75 FR 15376 at 15379). One comment suggests that safety information should be described in ways that are similar to the full FDA-approved product labeling. Another comment expresses concern about the potential for the example used in the proposed rule to evolve toward a general requirement to use more quantitative descriptors (e.g., frequency of risk, such as “more than half”) and the impact it might have on comprehension of risk information. Instead of a general requirement to use more quantitative descriptors, the comment requests a more case-specific approach applied on an ad-by-ad basis that could be objectively tested with the target audience to assess whether risk information is comprehended and understood.

Another comment recommends that FDA include clarification of appropriate threshold levels for quantifying risks for bothersome, significant, serious, or life-threatening risks attributable to the drug. The comment suggests that these thresholds be based on research in the field of risk communication to ensure that patients can interpret risk at the optimal level. The comment also notes that describing risks in quantitative terms may increase the conspicuousness of the risk information by drawing a consumer’s attention to the reality of the risk described and may provide consumers with an evidence-based presentation that is scientifically justifiable, increasing the neutrality of the ad.

(Response 11) We did not intend to propose, and have not included in the final rule, a general requirement that the major statement use quantitative descriptors. As we stated in the preamble of the proposed rule, “The major statement should also avoid the use of vague terms or explanations that are readily subject to different interpretations,” such as “*some*” (emphasis in original) (75 FR 15376 at 15379). Although this example involved quantitative terminology (“more than half”), we did not intend to require that the major statement always include quantitative descriptors but rather to clarify that to be “readily understandable,” the major

statement must avoid language or terminology that is so vague as to be readily subject to different interpretations.

H. Proposed Standard #2 (Final Standard #2) (Audio)--Comments and FDA Response

FDA proposed in § 202.1(e)(1)(ii)(B) that audio information in the major statement must be understandable in terms of the volume, articulation, and pacing used. This standard remains important for consumers to notice, attend to, and understand a drug's risk and benefits. We modified this standard in the final rule to clarify that the audio information presented during the major statement, in terms of the volume, articulation, and pacing used, must be at least as understandable as the audio information presented in the rest of the ad (standard #2).

(Comment 12) We received several comments supporting this proposed standard but also containing suggestions for improvement. One comment notes that proposed standard #2 is especially important to older adults or to consumers who, as a result of their literacy level or of visual or other limitations, may rely more heavily on the audio portions of an ad. Several comments note that the speed at which risk information in the major statement is presented in broadcast ads often makes it difficult to understand the information. One comment states that it is unacceptable for risk information to be “raced through as if being uttered by an auctioneer” and suggests that the pace of risk information should be identical to the pace of benefit information.

Two comments express concern that the proposed standards would increase the length of ads. One of these comments states that proposed standards #2 (audio information) and #3 (textual information) could impact the duration of an ad for a drug with substantial risk information.

(Response 12) We agree with the comments stating that this standard is especially important to consumers who may rely on the audio portion of an ad to understand the major statement, particularly older adults, as older adults watch more television (Ref. 41) and are more likely to take prescription drugs (Refs. 42 and 43). As such, this standard in the final rule

clarifies that the audio information presented during the major statement, in terms of the volume, articulation, and pacing used, must be at least as understandable as the audio information presented in the rest of the ad. The intention of this final standard is to ensure that the volume, pacing, and articulation of risk information presented in audio allow the information to be understood. Firms have an incentive to present the benefits of a drug in audio using volume, articulation, and pacing that ensure that those benefits are understood. Therefore, requiring that, in terms of these same attributes, the audio presentation of the major statement must be at least as understandable as the rest of the ad, will help ensure that the risk information in the major statement is similarly likely to be understood. This final standard provides a concrete way for firms to help meet the requirement that the major statement be presented in a clear, conspicuous, and neutral manner.

We disagree with the comments that assert that the rule will necessarily lengthen DTC TV/radio ads. As discussed in section V.K of this document (see comment 21), no comments, including those from industry, provided specific data, information, or examples of how the rule would require an increase in the length of these ads. FDA concludes that the rule will not require DTC TV/radio ads to be longer.

(Comment 13) One comment notes that the focus on volume, articulation, and pacing is important but overlooks the existing regulatory framework for the disclosure of risk information in DTC ads that results in a long disclosure of numerous risks, some of which are more relevant to the physician and to the patient-physician interaction once the decision has been made by the physician to prescribe a prescription drug product. This comment requests that FDA consider how much information is appropriate for the format.

(Response 13) The manner of presentation of the major statement is the focus of this rule. Neither the proposed rule nor this final rule changes the content of the major statement.

I. Proposed Standard #3 (Final Standard #4) (Presentation of Text)--Comments and FDA

Response

The third proposed standard for presenting the major statement in a clear, conspicuous, and neutral manner includes requirements for “[t]extual information [to] be placed appropriately and...presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily.” (See proposed § 202.1(e)(1)(ii)(C)). We revised proposed standard #3 (named final standard #4 in this final rule, codified as revised in § 202.1(e)(1)(ii)(D)) in response to comments, to clarify that the standard applies to the text portion of the major statement in TV ads and not to textual information in the TV ad generally. We have also removed the requirement for duration of display of text from this standard and address that topic in final standard #3, the dual modality standard. We also reorganized the remaining information in this standard for clarity. Like the corresponding standard of the proposed rule, final standard #4 is informed by relevant social science research as well as by the common themes seen in standards of other Federal agencies for “clear and conspicuous” disclosures (see Refs. 40, 44-50; 75 FR 15376 at 15377-15379).

(Comment 14) One comment is concerned that proposed standard #3 (final standard #4) could be interpreted to require that all major statements in all DTC ads in TV format include textual information. The comment recommends that FDA clarify the proposed standard for the manner of presentation of text in the major statement by inserting “if included” after “[t]extual information.” If information from the major statement is presented visually in text, the comment also questions how it should be presented with other information, such as “Available by prescription” or “See our ad in...”

(Response 14) Proposed standard #3 (final standard #4) addressed how to present textual information as part of the major statement, without requiring that any textual information be included. However, in this final rule, we require a dual modality presentation of the major statement for ads in TV format, through a separate standard. See section V.K of this document and § 202.1(e)(1)(ii)(C). We therefore decline to add the suggested phrase, “if included.” We agree that this final standard #4 does not alone create an obligation to present the major

statement using text, but we consider it applicable to any text used to present the major statement. We also revised language to clarify that this standard applies only to the text portion of the major statement in TV ads and not to other text. (Regarding the presentation of other information, see also section V.J of this document discussing final standard #5 (proposed standard #4) and addressing other audio or visual elements during the presentation of the major statement.)

(Comment 15) One comment says that the standard should take into account that many patients seeing broadcast ads, such as older adults and those with diseases that affect vision, may need larger letters or other accommodations. Two comments state that text placed in the lower portion of the TV screen is so small and rapidly displayed as to make information illegible. A few other comments request that FDA require firms to present risks in large, clear text, while another comment quantifies the preferred size of the text to be at least as large as 7 percent of the screen.

(Response 15) We agree that text used in presenting the major statement, including the font used, should allow the information to be read easily. We disagree that it is necessary to dictate a specific font size or other similar criterion. After considering comments, we conclude that this level of detail is unnecessary because there is more than one way to present the textual information that will allow the text to be read easily. Different presentational elements may interact and must be considered together, with more than one combination allowing for the textual information to be read easily. For example, increasing the amount of contrast between the font and the background may improve readability. And, even at a smaller size, some styles of font are more easily read compared to others. Duration of text is addressed in the final rule as an aspect of dual modality. (See discussion in section V.K of this document.)

(Comment 16) One comment expresses concern that proposed standard #3 is overly prescriptive and does not adequately take into account the limitations of using text in audio-visual media such as TV. The comment recommends that textual information be used as

secondary support to audio disclosure for the purpose of emphasizing particular risks when necessary. The comment further recommends a more objective, data-oriented approach to determine if information is understood and when text information might be useful to emphasize a specific point, rather than ensuring compliance with a specified text format.

(Response 16) We disagree with the portion of the comment stating that proposed standard #3 is “overly prescriptive.” Like its counterpart in the proposed rule, this standard in the final rule does not dictate particular font colors, sizes, placements, or backgrounds but instead requires that these aspects of text together result in an easily readable presentation. As suggested in comments, FDA intends these regulations to be flexible enough to allow for a variety of techniques firms may choose.

We disagree with the comment’s suggestion that text should be used to emphasize only particular risks rather than all risks contained in the major statement. We note that the major statement, to which the standards in this rule apply, is a selected presentation of the major side effects and contraindications of the drug and not a listing of every risk. In this final rule, we require a dual modality presentation (audio and text) of the major statement for ads in TV format, for reasons explained in section V.K of this document.

(Comment 17) One comment states that the proposed language about textual information being placed appropriately and being presented against a contrasting background is not consistent with the draft Risk Guidance. The comment asserts that the draft guidance recommends that risk information have a “comparable background.” The comment also requests alignment with the draft Risk Guidance or clarification regarding why there is a difference in opinion between the draft guidance and the proposed rule for presenting risk information in TV/radio ads versus through other media.

(Response 17) We conclude that the final rule’s requirement (that placement on the screen and contrast with the background, as well as size and style of font, enable the text portion of the major statement to be read easily) provides better assurance that the manner of the

presentation is clear, conspicuous, and neutral than the comment's proposed requirement of a "comparable background." Furthermore, contrary to the comment, we believe these aspects of the standard are consistent with the draft Risk Guidance, which was cited in the proposed rule as describing factors and supportive research consistent with the proposed rule's standards.

Specifically, with respect to the recommendations for non-print promotion such as TV ads and video, the draft Risk Guidance discusses the comparable presentation of risk and benefit information, not "comparable background" (Ref. 26, p. 15, line 528). In fact, in its specific discussion of visual elements in non-print promotions, the draft guidance also recommends that risk disclosures presented in SUPERS contrast with background visuals (Ref. 26, p. 20, line 676).

With regard to the comment's question about distinctions in presentation based on the medium used for the promotional communication, we note that the draft Risk Guidance addresses communications in the whole range of media; whereas, this rule is specific to DTC TV/radio ads. Characteristics of effective communication, including how consumers receive and understand information, can be impacted by different factors for each type of media, as reflected in the draft Risk Guidance recommendations and the research that guidance cites, as well as in the final standards established by this rule.

J. Proposed Standard #4 (Final Standard #5) (Elements That Interfere)--Comments and FDA Response

FDA proposed in § 202.1(e)(1)(ii)(D) that for a major statement to be presented in a clear, conspicuous, and neutral manner, the major statement must not include distracting representations (including statements, text, images, or sounds or any combination thereof) that detract from the communication of the major statement.

As described in section III.B of this document, in proposing this standard, FDA noted that the presence of distracting elements during the disclosure was one of several common themes addressed by standards of other Federal agencies to ensure that disclosures were "clear and conspicuous" (75 FR 15376 at 15378). FDA also noted that this standard (and the other

proposed standards) was consistent with the factors described and discussed in the draft Risk Guidance (75 FR 15376 at 15379). The standard we finalize in this rule is generally consistent with these approaches. We have modified this standard slightly from the proposed rule as a result of the comments received (and to help ensure effective communication).

In this final rule, we revised proposed standard #4, now final standard #5 (codified as revised in § 202.1(e)(1)(ii)(E)), to clarify that the standard is intended to preclude the use of audio or visual elements during the presentation of the major statement that are likely to interfere with comprehension of the major statement, but the standard does not address elements during other portions of the ad. Audio or visual elements may include, for example, music or other sounds, statements, text, and images. The standard does not categorically prohibit particular types of elements during the major statement but will be applied by considering the facts and circumstances presented by specific ads.

(Comment 18) Several comments support limiting distractions during the presentation of the major statement. One comment states that presenting the major statement without distraction is the key to improving audience understanding. Another comment says that distracting images or sounds can seriously undermine the clarity and conspicuousness of the presentation of risk information. One comment goes further and states that the major statement cannot be allowed to compete with distracting text, images, or sounds because it disrupts comprehension.⁶

Several comments say that implementing proposed standard #4 is particularly important because the visual depiction of benefits distracts from any simultaneous verbal presentation of risks, especially when the risk information is listed in a monotone or reassuring tone of voice. One comment argues that allowing positive scenes to be shown while presenting risk information has an adverse effect on a consumer's perception of the drug's risks. The comment suggests that FDA require a more restrictive standard limiting drug manufacturers from inserting the ads in an

⁶ The comment provided reference to Sorqvist, P., et al., "Individual Differences in Susceptibility to the Effects of Speech on Reading Comprehension," *Applied Cognitive Psychology* 24: 67-76, 2010, which concluded that irrelevant speech presented in audio disrupted reading comprehension.

overly positive environment or cheery setting and instead require that the text be displayed simultaneously with visual scenes that reinforce the risk.

Other comments express reservations about proposed standard #4. One comment states that proposed standard #4 could be misinterpreted to suggest that all representations are “distracting” and detract from communication of the major statement. The comment suggests that FDA revise this standard to clarify that it does not intend to prohibit all “representations,” including text, images, or sounds, during communication of the major statement. The comment suggests adding “certain” before “statements” and adding “significantly” before “detract.”

One comment states that it does not generally oppose the proposed standard but seeks clarification. In general, the comment interprets the proposed standard as intending to require “neutral” imagery. The comment opines that the concept of image neutrality is vaguely defined and subjective, requiring further definition in a final standard to avoid the risk it could be interpreted in an unnecessarily restrictive manner that would make DTC advertising impractical for pharmaceutical firms. More specifically, the comment understands the proposed standard to be intended to limit visuals that may be distracting during the major statement and interprets this to include specifically the types of positive images tested in the Distraction Study; however, it concludes that the study did not support the position that such images would impede the understanding of the safety information presented during the major statement. The comment also says that a restriction on positive imagery during the major statement could lead to a sterile “public service” style presentation of the messaging and limit its efficacy. The comment says that patient retention of messaging and motivation to learn more could be decreased because, the comment asserts, such messages would be less engaging and be ignored. The comment also says it is unclear to what degree “positive” imagery before and after the major statement would be allowable.

Another comment similarly expresses concern that proposed standard #4 could require firms to begin presenting risk information in a very bland manner that would be inconsistent with

the overall flow and tone of an ad, such that viewers may become disengaged with the ad when risk information is being communicated. The comment encourages FDA to study the impact of removing creative elements employed during communication of risk information and how it affects comprehension. This comment opposes including proposed standard #4 because, the comment opines, it is too subjective and likely inadequate as a surrogate for whether the target audience understands the risks communicated. The comment expresses concern that FDA would apply an overly prescriptive approach to evaluating proposed standard #4 and suggests instead an objective, science-based approach to evaluating audience understanding and comprehension of risk information.

(Response 18) We agree with comments that support the proposal to limit distractions during presentation of the major statement. Final standard #5 requires that during the presentation of the major statement, the ad does not include audio or visual elements (music, sounds, text, images, etc.) that, alone or in combination, are likely to interfere with comprehension of the major statement of risk information.

Several of the comments suggest a desire for clarification of the focus or scope of proposed standard #4 (final standard #5). Some are concerned that this standard precludes any elements during the presentation of the major statement at all, while others appear to equate this standard narrowly with the specific topics of study in the Distraction Study or the concept of “neutral” alone--none of which aligns with FDA’s intention. In response, in the final rule, we revised the wording to emphasize that in order to be presented in a clear, conspicuous, and neutral manner, during the presentation of the major statement, the ad must not include audio or visual elements that, alone or in combination, are likely to interfere with comprehension of the major statement. We conclude that the revised wording of this provision better captures the standard for determining whether an element or a combination of elements distracts from the mandatory presentation of the major statement. The changes to the wording of final standard #5 also clarify that this requirement applies during the limited part of the ad that presents the major

statement, not to other portions of the ad. This standard independently contributes to achieving a clear, conspicuous, and neutral manner of presentation of the major statement, adding to the effect of other standards in this rule.

We do not conclude that all audio or visual elements are likely to interfere with comprehension of the major statement. In fact, as addressed in section V.K of this document, in the final rule, by requiring dual modality--the concurrent use of both text (a visual element) and audio to present the major statement in ads in TV format--we acknowledge that multiple elements can actually be used to reinforce risk information.

This standard does not categorically prohibit use of other creative elements during the major statement, nor does it prohibit narrower categories of such elements (e.g., it does not bar music, sound effects, or drawings). The standard does not even categorically prohibit any subtypes of elements (e.g., it does not bar upbeat music or amusing drawings). Notably, the standard does not categorically prohibit visual depictions of benefits or positive imagery during presentation of the major statement in TV ads.

It is not our intent that the major statement be presented in a bland manner such that the audience becomes disengaged during this part of the ad, nor do we intend to require a “tombstone” presentation of the major statement. Rather, final standard #5 is a common-sense measure that adds to the others to help ensure that consumers notice, attend to, and understand the major statement by prohibiting the simultaneous presentation of other audio or visual elements, alone or in combination, that are likely to interfere with comprehension of the major statement. This requirement applies only during the limited portion of the ad that presents the major statement and places no restrictions on any other part of the ad.

(Comment 19) Several comments discuss what effect the results of the Distraction Study should have on FDA policy regarding proposed standard #4 (final standard #5). One comment argues that design flaws resulted in the failure of the Distraction Study to detect any significant effects upon risk comprehension resulting from various forms of distraction; therefore, the

results must be disregarded. Another comment states that the Distraction Study did not appear to provide an adequate factual or rational basis upon which FDA can rely to augment FDA's authority with respect to final standard #5 and the entire rule. One comment states that certain design characteristics of and results from the Distraction Study raise significant questions about its utility to support regulatory decision making. Another comment states that after reviewing the results of the Distraction Study, any additional restrictions imposed on the clear, conspicuous, and neutral standard would only "muddy the waters" and that a broad requirement, with as little nuance as possible, would enable the Agency to determine, unhindered, that a particular ad committed a violation of the clear, conspicuous, and neutral requirement. One comment says that in light of the results of the Distraction Study, it seems that the only way to present the risk information is to require a standard format for conveying risks. Experts could then continuously evaluate the standard format and determine whether it was the most effective method to convey the risk information.

(Response 19) Final standard #5 rests on a well-established principle that presenting more than one element during the same period of time, in some cases, interferes with comprehension of information. This is often referred to as "distraction." As manifested in numerous other Federal disclosure standards (see 75 FR 15376 at 15377), in order to support the effective presentation of required disclosures, it is important to avoid distractions.

Addressing this concern is especially important in the ads in TV/radio format that are subject to this rule because these ads are fleeting--appearing for a brief interval in the midst of other content--and within each ad's overall running time, consumers typically do not control how much time they have to absorb the information from the major statement. For example, the average length of ads in TV format is between 30 and 60 seconds overall.⁷ In prescription drug

⁷ A 5-year study by DRMetrix included data from 2015 to 2018 and captured a total of 50 million DTC TV ad presentations. The study evaluated the frequency with which different lengths of TV ads were run. Ads of 30 seconds in length were run the most. See "5 x 5 Industry Study," DRMetrix, 2019, available at https://www.drmetrix.com/public/5_x_5_Industry_Study_Oct_2019.pdf.

ads, the presentation of the major statement occupies only a part of the ad, so in a 30- or 60-second ad, consumers are not given much time to notice and understand that important information. If, during the presentation of the major statement, the consumer's attention is instead focused on other elements of the ad, the major statement may be relayed without being understood.

The possibility of distraction interfering with comprehension is apparent from ordinary experience, and it is also amply supported by social science research. For example, visual and auditory elements that have been shown to detract from or interfere with the communication of information and viewer comprehension include noise, loud music, and rapid scene changes (Refs. 34, 35, 38, 39, 51-53). The reasonable approach embodied by final standard #5 is to assess, case-by-case, the particulars of a specific ad to determine whether, during the presentation of the major statement, it includes audio or visual elements that, alone or in combination, are likely to interfere with comprehension of the major statement.

We rely on the existing substantial body of literature regarding distraction as the basis for final standard #5, not FDA's Distraction Study, contrary to the implication of some comments. As previously addressed (see section V.C of this document), FDA's Distraction Study was not an investigation of all elements or factors that can contribute to distraction. The Distraction Study was designed only to examine the effects of three particular, pre-defined factors: (1) the presence or absence of SUPERS that concurrently presented verbatim, key words and phrases from the audio presentation of risk; (2) variations in the positive (affective) tone of visual images; and (3) visual information that was either inconsistent or consistent with the audio risk information. With regard to factor 2, this research investigated a hypothesis that the visual depiction of positively toned imagery during the simultaneous audio presentation of risk information would interfere with comprehension of the risk information. Although study participants in the strongly positive tone conditions showed lower risk comprehension than participants in the mildly positive tone conditions, this difference was not statistically significant.

As a result, the Distraction Study did not find support for the hypothesis that the visual depiction of positively toned imagery interferes with the comprehension of risk information in the major statement. Therefore, conclusions about the effect of positively toned imagery on risk comprehension cannot be drawn from this study.

Nonetheless, FDA's Distraction Study did not call into question the substantial body of literature on different and more obvious types of distractions (e.g., noise, loud music, rapid scene changes); this study did not include and was not designed to test these well-known types of interferences. Thus, we rely on the existing substantial body of literature on this topic to support standard #5 in the final rule.

We also disagree with the comment that suggests FDA might use the Distraction Study to "augment" its authority. Congress passed a law requiring that the major statement relating to side effects and contraindications in DTC TV/radio ads be presented in a "clear, conspicuous, and neutral" manner, and Congress directed FDA to issue standards for determining whether a major statement is presented in this manner. Final standard #5 (as well as the other final standards in this regulation) is consistent with this grant of statutory authority.

K. Dual Modality (Final Standard #3)--Comments and FDA Response

In the proposed rule, FDA solicited public comment on whether to require that the major statement in ads in TV format be included in both the audio and visual parts of the presentation (dual modality) (75 FR 15376 at 15380). We referenced the FTC standard for determining whether an affirmative disclosure in a television commercial is clear and conspicuous, which states that for disclosures in a television advertisement to be clear and conspicuous, they should be presented simultaneously in both the audio and video (75 FR 15376 at 15377, 15380). In addition, we referenced research specifically conducted on the subject of dual modality in advertising that supported the use of simultaneous presentations of key words or full sentences in text with the corresponding key words or full sentences in audio to aid in processing (75 FR 15376 at 15383), as well as a broader body of research that supports the use of dual modality in a

wide variety of situations (75 FR 15376 at 15383-15384).⁸ We also reopened the docket in 2012 to include the report of the Distraction Study that investigated dual modality presentation of the major statement in TV ads (among other things) and we requested comments on the results of that study as those results related to the proposed standards. As summarized in the document reopening the comment period--and further detailed in the study report in the docket--the study indicated that presenting the same risk information at the same time in text and in audio improves consumer understanding of the risk information (see 77 FR 4273-74; Ref. 27). Thus, the results of FDA's Distraction Study regarding the effects of dual modality on comprehension of risk information were in line with the studies described in the 2010 proposed rule. Not only did the Distraction Study find that presenting the same risk information at the same time in text and in audio improved risk comprehension, but it also found that presenting risk information in dual modality was not associated with any reduction in comprehension of benefits (Ref. 27). Subsequent research (Refs. 53-56) corroborates the evidence--originally discussed in the proposed rule and again in the Distraction Study report that was made available for public comment--that presenting information in both audio and visual (dual modality) improves comprehension of the information provided. The comments we received helped inform our decision to require dual modality in this final rule, supported by the Distraction Study research and subsequent research and literature.

The majority of comments on this topic support dual modality, while a few comments opposed it.

(Comment 20) Overall, the comments addressing dual modality favor the implementation of this standard. Comments note that dual modality will help improve consumer understanding of the risk information and help make a lasting impression on consumers. Comments also noted

⁸ For additional corroboration, also see Murray, N.M., L.A. Manrai, and A.K. Manrai, "Public Policy Relating to Consumer Comprehension of Television Commercials: A Review and Some Empirical Results," *Journal of Consumer Policy*, 16(2):145-170, 1993; Tindall-Ford, S., P. Chandler, and J. Sweller, "When Two Sensory Modes Are Better Than One," *Journal of Experimental Psychology: Applied*, (3):257-287, 1997.

that dual modality would account for consumers with different learning styles and pointed out that research supports dual modality. Additionally, comments noted that FTC has a similar standard and that including the dual modality standard would provide firms with direction on how to properly adhere to the “clear, conspicuous, and neutral” requirements. One comment gives certain critiques of the Distraction Study’s methodology but ultimately supports a dual modality requirement.

Comments that oppose dual modality assert that it is unnecessary and could distract consumers or have potentially negative consequences. One of these comments states that presenting complex clinical risk information simultaneously in both the audio and text could prevent consumers from effectively receiving this crucial information from either mode of communication. This comment says that viewers who focus on the audio component might assume that the text qualifies the audio message, leaving them to question the veracity of whatever portion of the major statement they processed and understood.

One comment says that even though the Distraction Study suggests that in some contexts it may be possible to improve comprehension of benefit and risk information through a dual modality requirement, there are significant questions regarding the interpretability of that data. Consequently, the comment claims that the Distraction Study was not robust enough to support imposing a dual modality requirement in FDA’s regulation. The comment argues that although the difference in risk comprehension between the no SUPERs cohort and the combined large and small SUPERs cohorts in the Distraction Study appears to be statistically significant, there is no indication that it is significant from a clinical or regulatory point of view. The comment states that even if FDA’s study showed that consumers had better risk comprehension when SUPERs were used, it does not follow that ads that do not use SUPERs are: (1) false, misleading, or otherwise lacking in fair balance or (2) not clear, conspicuous, or neutral. The comment argues that ads both with and without SUPERs could be legally acceptable. Therefore, according to the

comment, the Distraction Study may provide useful information regarding optimal advertising practices, but it does not provide information that is relevant from a regulatory perspective.

The comment also states that the Distraction Study does not foreclose the possibility that other advertising techniques, either alone or in combination, may be as effective or even more effective than a dual modality requirement in optimizing comprehension of risks and benefits and rendering the major statement “clear, conspicuous, and neutral.” The comment states that advertisers should have regulatory flexibility in designing DTC TV ads in a manner that complies with applicable requirements to communicate risks, without FDA imposing a dual modality requirement.

One comment opposes dual modality, arguing that it does not improve consumer recall or understanding of important risk information in DTC ads. The comment describes research that the submitting firm undertook in 2005, the results of which suggest that recall of risk and benefit information does not vary in consistent or systematic ways according to ad risk presentation or execution, including when dual modality is used to present major risk terms. The comment also states that the limitations of this study may have affected observed results. The same firm subsequently submitted the results of additional research it undertook several years later, described further in the response to this comment, which do support a dual modality requirement.

(Response 20) We have included a dual modality requirement in this final rule (§ 202.1(e)(1)(ii)(C)) after consideration of comments we received, as well as research and literature supporting the positive impacts of dual modality on risk comprehension and recall that existed at the time of the proposed rule. Notably, as detailed further in section V.K of this document, subsequent research corroborates these earlier findings on the positive impact of dual modality on recall and comprehension of risk. Under this standard, for the major statement of an ad presented in TV format to be presented in a clear, conspicuous, and neutral manner, it must be presented concurrently using both audio and text (dual modality). To achieve dual modality, the regulation establishes further specific standards for the display of text. First, either the text

displays the verbatim key terms or phrases from the corresponding audio, or the text displays the verbatim complete transcript of the corresponding audio. Second, the text must be displayed for a sufficient duration to allow it to be read easily. Under the final regulation, for purposes of this standard, duration of the text display is sufficient if it begins at the same time and ends at approximately the same time as the corresponding audio. These duration and display characteristics are supported by the research studies that evaluated concurrent text and audio presentations (dual modality), discussed in the proposed rule and in section V.C of this document. Moreover, as discussed in section V.K of this document, other research subsequently corroborated these research findings regarding the positive impact of dual modality on consumer recall and comprehension.

We do not agree with the comment suggesting that dual modality could prevent consumers from effectively receiving risk information. No references were provided to support this assertion. To the contrary, as discussed in the preamble of the proposed rule (75 FR 15376 at 15383-15384), research shows that using audio and visual presentations to present the same information at the same time increases comprehension compared to using only one mode (See also Refs. 57 and 58). Research demonstrates improved recall when reinforcing SUPERs are used, and suggests that a dual mode of presenting information results in greater recall and comprehension in a wide variety of situations (Refs. 53, 59, and 60-64). The positive impact of dual modality on recall and comprehension has been further demonstrated through subsequent research (Refs. 54-56).

FDA's Distraction Study examined, in part, how an ad's SUPERs might influence understanding of the risk information in the audio portion of the ad. As summarized in the *Federal Register* document reopening the docket to solicit comments on the results of this study as related to the proposed standards (77 FR 4273-74) and further detailed in the study report in the docket (Ref. 27), we found that presenting the same risk information at the same time in text and in audio improves consumers' understanding of that risk information compared to audio

alone. This finding is statistically significant and consistent with prior research. The Distraction Study also found that there was no tradeoff to the presentation of risk using dual modality in regard to comprehension of benefit; the increase in risk comprehension was not associated with any reduction in benefit comprehension (Ref. 27).

As noted previously, research results submitted by a firm had similar findings about use of dual modality. The firm undertook research to determine how dual modality might affect consumers' recall and comprehension of information in the major statement of prescription drug TV ads. The firm's research results demonstrated that dual modality increased risk recall and understanding of risks. The results also demonstrated that dual modality did not decrease consumer recall and understanding of product benefits. Whether the full text of the risk statement or keywords were presented visually did not affect recall and comprehension of risk information. This submitted research corroborates other research in the record.

(Comment 21) One comment asserts that the proposed rule was unclear regarding "what specific information from the major statement should be presented visually or how that visual information should be presented with other information, such as 'Available by prescription' or 'See our ad in Health magazine.'" The same comment questions whether FDA would require "a simultaneous, verbatim presentation" of the major statement in the audio and video or only require the firm to use each mode to present the major statement at some point in the ad. It further asserts that regardless of whether dual modality requires simultaneous presentation of the major statement in both audio and text, a visual presentation of the major statement would need to appear on screen for a significant portion of many ads to allow consumers of all abilities sufficient time to read and absorb the risk information, which in turn might overemphasize risk information and thus result in the non-neutral presentation of that risk information. That comment also suggests that to meet a dual modality requirement, TV ads would necessarily grow in length to accommodate required additional text. However, another comment says that fulfilling a dual modality requirement would not require more ad time, and in fact, requiring

audio and visual presentation of the major statement to occur at the same time might even reduce ad length. A third comment expresses the view that, to improve consumer risk awareness, the regulation should require that the major statement be presented in dual modality, using text that is either identical to the audio track or an abbreviated, easily processed bullet point type of text, using only words that occur in the audio track.

(Response 21) To reinforce the presented risk information and consequently help improve its comprehension, the final rule requires the concurrent presentation of the major statement in the audio and in text. This is consistent with the proposed rule, which reflected the expectation that where text was used, it would appear “concurrently with any directly related audio information” (75 FR 15376 at 15379) as well as with the research cited in the proposed rule (75 FR 15376 at 15383). This is also consistent with the FTC standard, cited in the proposed rule, for determining whether an affirmative disclosure in a television commercial is clear and conspicuous, which states that for disclosures in a television advertisement to be clear and conspicuous, they should be presented simultaneously in both the audio and video (Ref. 65) (75 FR 15376 at 15377 and 15380). Further, the final rule provides additional clarity on how to achieve a dual modality presentation of the major statement regarding what text must appear, when the text must appear in relation to the audio, and for what duration--consistent with research cited in the proposed rule (75 FR 15376 at 15383) and the approach used in the Distraction Study, the report of which was placed in the docket and the comment period reopened expressly to solicit comment on the results of that study in relation to the proposed standards (77 FR 4273-74; Ref. 27). The provisions in the final rule collectively provide considerable flexibility to firms and do not necessitate that the textual presentation of the major statement remain on screen throughout the ad.

We agree with the comment noting that the text used to achieve dual modality should present words that the corresponding audio uses, rather than synonyms, and also agree that dual modality can be achieved using text in an abbreviated form. This is consistent with the

approaches used in research that was cited in the proposed rule and that supported dual modality (75 FR 15376 at 15383), as well as the approach used in the Distraction Study (Ref. 27).

Accordingly, the final rule specifies that dual modality can be achieved either by displaying the verbatim key words or phrases from the corresponding audio or by displaying the verbatim complete transcript of the corresponding audio. This provides firms flexibility to choose from various presentation options. For example, if the audio states, “The most common side effects of DRUGX are dry mouth, headache, and heartburn,” instead of presenting a complete verbatim transcript of that statement, the accompanying text could present bullets stating “• dry mouth • headache • heartburn.”

The final rule also addresses the duration of text display. Like proposed standard #3 (which alone would not have required text, but addressed how to present text if it were used in addition to the already-required audio to present the major statement), the final rule requires that text used to present the major statement be displayed for a duration that allows it to be read easily. Discussion of proposed standard #3 also indicated our intention to require that visually-presented text information from the major statement appear “concurrently with any directly related audio information” (75 FR 15376 at 15379). These elements of proposed standard #3 regarding the display of text are now picked up as part of the dual modality requirement (final standard #3). Final standard #3 clarifies their relationship to each other and to the audio presentation requirements of the rule, stating that the duration of display of text is sufficient if it starts at the same time and ends at approximately the same time as the corresponding audio. This approach is similar to that required for the presentation of closed captioning under Federal Communication Commission regulations. See 47 CFR 79.1(j)(2)(ii). In turn, the pace of the audio component of the major statement is determined by the requirement that the audio information be at least as understandable as the audio information presented in the rest of the advertisement that the firm chooses. (See final standard #2 (§ 202.1(e)(1)(ii)(B)) and section V.H of this document.) With this flexibility, we believe the presentation of risk information will not

be overemphasized. None of the standards of the final rule that impact duration of text display, including the dual modality standard, either separately or together, require that the textual presentation of the major statement remain on screen throughout the ad or generally require increasing the length of ads in order to present the major statement. At the same time, we think the methods of achieving dual modality described by the rule will contribute to presenting the major statement in a clear, conspicuous, and neutral manner.

L. First Amendment Freedom of Speech--Comments and FDA Response

Two comments question whether the proposed rule is consistent with First Amendment protections for freedom of speech. One addresses the major statement's requirement to disclose side effects generally; the other focuses on the proposal for presenting the major statement using dual modality.

(Comment 22) One comment asserts that the overall requirement for the major statement to disclose side effects is unconstitutional under the Supreme Court's decision in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980), regarding commercial speech restrictions, but the comment does not address any specific elements of the proposed manner of presentation that are the subject of this rulemaking. This comment asserts that, for the Government to restrict advertising, among other things, the advertising must be misleading, and the comment states without elaboration that "lack of disclosure or lack of clarity" of side effects does not make advertising misleading. The comment also asserts that the Government has no substantial interest in mandating disclosure of risk information in DTC ads in TV/radio format and, consequently, that no requirements for a major statement in a DTC ad could satisfy the First Amendment. The comment states that the Government interest implicated by requiring disclosure of side effects in DTC prescription drug advertising is one intended to protect consumer safety but that this interest "cannot be proven as substantial" because it is already addressed by the requirement to obtain a prescription to access a prescription drug. The

comment further suggests that the information is unnecessary in ads because all prescription orders explain drug side effects.

Another comment raises concerns that a dual modality requirement would violate the First Amendment. The comment suggests that the proposed dual modality requirement is subject to First Amendment analysis under *Central Hudson* and under *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), and also suggests that “a regulatory scheme that formats the style and content of advertising in advance of its presentation to the public” might impose an unlawful prior restraint on advertising. In addition, the comment asserts that to hold a firm liable for failing to use dual modality, FDA would have to prove that absent dual modality, the ad would be false or misleading to the consumer, noting that a consumer cannot obtain a prescription for an advertised drug without consulting a physician. The comment suggests that, unless FDA can establish in advance that all ads that lack dual modality would be false or misleading, the dual modality requirement is not constitutional.

(Response 22) We disagree that the major statement requirement as a whole, the dual modality requirement in particular, or any other aspect of this rule’s standards for presenting the major statement in a clear, conspicuous, and neutral manner violates the First Amendment.

As the Supreme Court has explained, Government mandates for “health and safety warnings” have been “long considered permissible,” and these warnings as well as “purely factual and uncontroversial disclosures about commercial products” are legal under the First Amendment (*Nat’l Inst. of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2376 (2018)). The presentation of the major statement addressed in this rule, as well as the underlying requirement to provide the important side effects and contraindications of the drug, fall squarely within these categories.

Specifically, the major statement is quintessential health and safety warning information, reflecting the contraindications and side effects of a prescription drug as described in the prescription drug’s approved labeling. The content of the major statement is not changed by this

rulemaking. As explained in section III of this document, there is a long history of requirements to provide health and safety warnings about a prescription drug's risks, including in its advertising, and to ensure that understanding of required disclosures about these products is not undermined by an inadequate manner of presentation of the information.

More generally, the major statement is a factual disclosure about a commercial product to be included in its advertising. The Supreme Court examines factual disclosures about products and services in commercial speech under the analysis in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985). See *Nat'l Inst. of Family and Life Advocates*, 138 S. Ct. 2361, 2377-2378; *Milavetz, Gallop & Milavetz, P.A. v. United States* 559 U.S. 229, 250, 252-253 (2010). Under the approach articulated in *Zauderer*, courts have upheld required disclosures of factual and uncontroversial information about a product or service in commercial speech about that product or service. See, e.g., *American Hosp. Ass'n*, 983 F.3d 528, 540 (posting negotiated rates for hospital services); *American Meat Inst. v. Dept. of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (en banc) (country of origin labeling for meat); *N.Y. State Restaurant Ass'n v. N.Y.C. City Bd. of Health*, 556 F.3d 114 (2d Cir. 2009) (calorie information on menus); *Nat'l Elec. Mfrs. Ass'n*, 272 F.3d 104 (labeling identifying presence of mercury in light bulbs). Where such disclosures are not unjustified or unduly burdensome, their imposition does not offend the First Amendment. See, e.g., *Nat'l Inst. of Family and Life Advocates*, 138 S. Ct. 2361, 2377-2378; *American Hosp. Ass'n*, 983 F.3d 528, 541 (required publication of standard charges is not unduly burdensome in a way that chills commercial speech as it “neither requires hospitals to endorse a particular viewpoint nor prevents them from adding their own message on the same website or even in the same file”; alleged financial burden of compliance with the disclosure requirement not established to be burden on speech); *Spirit Airlines, Inc. v. United States Dep't of Transp.*, 687 F.3d 403, 414 (D.C. Cir. 2012) (requirement for airlines to make total price the most prominent cost figure does not significantly burden airlines' ability to advertise); *Discount Tobacco City &*

Lottery, Inc., 674 F.3d 509, 524 (size of required tobacco warnings is not unduly burdensome where remaining portions of their packaging are available for other information).

The provisions of this rule likewise satisfy the requirements of *Zauderer* and subsequent cases. First, the required information about the drug's side effects and contraindications presented in the major statement is factual and uncontroversial. As already noted, it is derived from the drug's FDA-approved labeling, which is based on data and information about the product submitted by the drug's sponsor and evaluated by FDA.

Second, requiring that this information be presented in DTC TV/radio ads in a clear, conspicuous, and neutral manner is justified by the interests described in section III of this document. Contrary to the implications of both comments, the substantial Government interests supporting these measures are not limited to preventing consumers from being misled or protecting consumer safety. Rather, the substantial Government interests underlying this rule also include helping to ensure consumers are better informed when they participate in healthcare decision making, including when no HCP is present (see discussion in section III.A). Communicating risk information in a manner that improves the likelihood that consumers notice, attend to, and comprehend that information is instrumental to advancing this purpose of including risk information in the first place. See *Discount Tobacco City & Lottery, Inc.*, 674 F.3d 509, 561-564 (enhanced warnings on tobacco products advance the interests in promoting greater public understanding of the risks of those products; "A warning that is not noticed, read, or understood by consumers does not serve its function").

Third, this rule is not unduly burdensome. The final rule's requirements for the manner of presenting the major statement--including the requirement for dual modality--do not threaten to drown out or chill the firm's other messages. Indeed, the firm not only remains free to present other messages in the ad; under this rule, it retains substantial ability to choose how to present the major statement.

For example, the major statement has long been required to be presented in audio. This rule provides more direction on how to do so but leaves many implementation details up to the firm. With regard to this audio presentation, the final standard requires that the volume, articulation, and pacing make the audio presentation of the major statement “at least as understandable as the audio presented in the rest of the advertisement” (§ 202.1(e)(1)(ii)(B))-- leaving it substantially up to the firm how it wants to use audio for all the content in the ad. To fulfill the dual modality requirement for ads in TV format, the display of text is sufficient if it begins at the same time and ends at approximately the same time as the corresponding audio and displays the verbatim key terms or phrases from the corresponding audio (§ 202.1(e)(1)(ii)(C)). Ultimately, then, this final rule, including dual modality, retains the firm’s substantial control of the overall presentation and duration of the major statement and preserves the firm’s opportunity to present the advertised drug’s benefits or any other messages in other parts of the ad. And, as discussed in section V.K of this document, the use of dual modality does not decrease the recall or comprehension of benefit information even while it improves consumer comprehension and recall of the risk information, advancing the Government interests discussed in section III.A.1 of this document.

While we conclude that *Zauderer* provides the relevant framework for analysis of the mandatory risk disclosure provisions of this rule and that its requirements are satisfied, we also conclude that this rulemaking is consistent with the First Amendment if analyzed under more exacting scrutiny, including *Central Hudson*, a case mentioned by both comments. Contrary to the implication of both comments, FDA’s authority to regulate prescription drug advertising is not limited to cases in which that speech is misleading (or false). Rather, under the *Central Hudson* framework, even if commercial speech is truthful, is not inherently or actually misleading, and relates to lawful activity, the Government may impose restrictions that directly advance a “substantial” Government interest and are no “more extensive than is necessary to serve that interest” (*Central Hudson Gas & Elec. Corp.*, 447 U.S. 557, 566).

In cases examining limitations on commercial speech, the Supreme Court has endorsed “the principle that disclosure of truthful, relevant information is more likely to make a positive contribution to decisionmaking than is concealment of such information” (*Peel v. Attorney Registration and Disciplinary Comm’n of Illinois*, 496 U.S. 91, 108 (1990)). As a result, the Court has favored use of disclosures over restrictions on speech to advance the substantial interests in preventing consumers from being misled and in making a positive contribution to informed decision making (*id.* at 109-110); *Shapiro v. Kentucky Bar Ass’n*, 486 U.S. 466, 477-478 (1988); *In re R.M.J.*, 455 U.S. 191, 203 (1982); *Bates v. State Bar of Arizona*, 433 U.S. 350, 375 (1977); *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 770 (1976).

Similarly, the FD&C Act and FDA implementing regulations require disclosures of risk information where prescription drug ads promote the product’s benefits to directly advance the substantial Government interests previously described in section III of this document. The requirements in this rule to ensure that important facts about the risks of an advertised drug are presented in a clear, conspicuous, and neutral manner in its DTC TV/radio ads are reasonable in proportion to these interests and thus present no constitutional infirmity under any potentially applicable First Amendment standard.

Three of the standards for presenting the major statement address basic techniques for any communication targeting a broad consumer audience: that it uses consumer-friendly language and terminology, rather than technical language; that its audio be at least as understandable as other audio in the same ad; and that the visual aspects of text used to present the major statement allow that text to be read easily. (See § 202.1(e)(1)(ii)(A), (B), and (D).) The two remaining standards likewise are appropriately tailored to the interests behind the rule and do not unreasonably burden speech. Dual modality has already been discussed, and as noted, research indicates that using this technique to present risk information improves consumer risk comprehension and recall--advancing the Government interest--without decreasing the recall

or comprehension of benefit information, thus reinforcing the reasonableness of this requirement.

(See § 202.1(e)(1)(ii)(C).)

The last standard, in § 202.1(e)(1)(ii)(E), is a common-sense measure that adds to the others to help ensure that consumers notice, attend to, and understand the major statement by prohibiting the simultaneous presentation of other audio or visual elements, alone or in combination, that are likely to interfere with comprehension of the major statement. This requirement applies only during the limited part of the ad that presents the major statement, placing no restrictions on any other part of the ad. Even during the presentation of the major statement, it does not categorically prohibit other audio or visual elements. In sum, these measures to advance the substantial Government interests in communicating the major side effects and contraindications of a prescription drug advertised to consumers satisfy the framework for analysis described in *Central Hudson* and are consistent with the First Amendment.

FDA has considered and rejects the suggestion in the comments that the Government interests that justify this rule are adequately advanced by the requirement to obtain a prescription from an HCP to access a prescription drug. The comments do not recognize consumers as active participants in their own healthcare, and do not address the Government interest in helping to ensure that consumers are better informed when they participate in healthcare decision making. This Government interest is not completely or sufficiently addressed by the requirement to obtain a prescription or visit an HCP before accessing a prescription drug. Both before and after contact with an HCP, consumers are frequently exposed to DTC TV/radio ads describing the drug's benefits. Requiring that such ads also convey the advertised product's risks better advances the substantial Government interests than reliance on the HCP alone. For example, for a patient already taking a prescribed drug, certain side effects may occur at any time, and presenting information about that drug's risks in DTC ads provides the patient with information about the side effects each time they encounter the ad. Providing this information helps ensure

that consumers are better informed about side effects that they may experience in connection with their use of the drug. Furthermore, the assumption in comments that HCPs or “prescription orders” will communicate prescription drug risks to consumers does not dispute that consumers should be informed of those risks. Rather, it appears to suggest that it is appropriate for a pharmaceutical firm to benefit from advertising its prescription drug’s positive attributes directly to consumers while placing the entire burden of informing consumers about that advertised drug’s risks on other members of the healthcare system. The First Amendment does not compel us to adopt that policy.

One of the comments also cited *Western States*, in which the Court applied the *Central Hudson* test to evaluate the advertising restriction at issue (535 U.S. 375 at 368-77). In an analysis that broke no “new ground” (id. at 368), the Court explained that, in general, the Government should not restrict the communication of truthful and non-misleading information for the sole purpose of preventing members of the public from making bad decisions with the information (id. at 374). That holding and rationale has no application to this rule, where formatting and presentation requirements help ensure the effective disclosure of information to the public.

Finally, with regard to the mention of prior restraint in the context of the comment on dual modality, we disagree that this rule presents any constitutional infirmity under that analysis. The fundamental concern of the prior restraint doctrine is with Government censorship in advance of publication. See *Southeastern Promotions, Ltd. v. Conrad*, 420 U.S. 546, 553 (1975). Here, however, neither the dual modality requirement nor any other aspect of this rule requires a firm to seek any permission from FDA before running an ad or otherwise enjoins speech before it occurs, and therefore the regulation does not impose a prior restraint. See, e.g., *Alexander v. United States*, 509 U.S. 544, 549-553 (1993).

M. Role of Healthcare Professional--Comments and FDA Response

(Comment 23) One comment asserted that too much information in the major statement can make it difficult for the audience to comprehend the information and that the role of the prescribing HCP as a learned intermediary is an important consideration in determining the relevancy of risk information to be included in a DTC broadcast ad.

Another comment says that because doctors are responsible for their patient's care and well-being, prescription drug ads should be required to include--“instead of a clear, conspicuous, and neutral statement of effects and contraindications”--a statement “that only a patient's doctor can fully provide this vital information.”

(Response 23) This rulemaking does not change the content of the major statement, but focuses on the manner of presenting it in DTC TV/radio ads. Further, FDA acknowledges the role of HCPs regarding prescription drugs; however, as discussed in section III.A of this document, that role does not completely address the reasons to require prescription drug firms to communicate risk information about their products in a clear, conspicuous, and neutral manner in DTC TV/radio ads that communicate the benefits of such products.

N. Costs--Comments and FDA Response

(Comment 24) One comment states that the specific dollar estimates to revise any ad with a life cycle extending beyond the compliance date of the final rule were optimistically low and questions how FDA or its industry sources arrived at these estimates. Furthermore, the comment requests that FDA revisit the cost estimates (and publish a more detailed analysis) to make certain that they accurately reflect the costs that firms will incur in bringing their existing campaigns into compliance. As part of addressing costs, the comment requests that FDA consider a longer effective date.

(Response 24) No comments included quantified costs that firms will incur in bringing their existing campaigns into compliance. With regard to the request for an updated estimate of costs, we direct readers to the Regulatory Impact Analysis (Ref. 66), which evaluates the anticipated costs to firms for complying with this rule. In light of concerns regarding costs, FDA

has agreed to a compliance date of 365 days after the date of the final rule publication for all ads. (See section VI of this document.)

O. Enforcement--Comments and FDA Response

(Comment 25) One comment suggests that FDA should enforce these standards through civil monetary penalties (CMPs) for misleading DTC advertising, as authorized under 21 U.S.C. 333(g)(1).

(Response 25) Failure to follow this rule will render a drug misbranded under 21 U.S.C. 352(n). The Agency will have all compliance tools associated with its authority available to enforce these provisions; see generally the FD&C Act sections 301 (prohibited acts), 302 (21 U.S.C. 332) (injunction proceedings), and 303 (penalties), including, as applicable, CMPs for false or misleading DTC ads authorized under section 303(g)(1) of the FD&C Act (21 U.S.C. 333(g)(1)).

VI. Effective/Compliance Dates

This rule is effective [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The compliance date is [INSERT DATE 365 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

As described in the proposed rule, in accordance with FDAAA, the statutory requirement that the major statement in human prescription drug advertisements presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use be presented in a clear, conspicuous, and neutral manner has been in effect since March 25, 2008 (75 FR 15376 at 15380). In the proposed rule, FDA proposed that the standards in the final rule would become effective 90 days after the publication of the final rule in the *Federal Register*.

(Comment 26) One comment supports the 90-day proposal. Two comments request the earliest possible implementation of the proposed standards. Another comment agrees that 90 days is reasonable for DTC ads that have not already begun production. However, the comment

suggests 180 days for ads that are already in production or circulation because it allows time for modifications if required.

(Response 26) Based on comments, FDA agrees that it is appropriate to provide a longer period for implementation than originally proposed. We therefore make the effective date 180 days after publication. Affected firms are encouraged to comply as soon as possible after the effective date. However, we recognize that this rule could impact existing ads, ads in production, and distribution agreements. Accordingly, we now conclude that a compliance date of 365 days after the date of publication of the final rule is appropriate to enable firms to bring all ads subject to this rule into compliance without undue burden. One schedule of 365 days after publication of the final rule for compliance is clearer and easier to administer than having two different schedules depending on where the ad is in production or on other factors. While we did not receive data to support an alternative estimate of costs, given the complexities of distribution agreements and concerns raised with costs, we have also determined that a longer time for implementation is appropriate.

VII. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866, 13563, and 14094, direct us to assess all benefits, costs and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are “significant” under Executive Order 12866, section 3(f)(1) (as amended by Executive Order 14094), if they “have an annual effect on the economy of \$200 million or more (adjusted every 3

years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.” OIRA has determined that this final rule is not a significant regulatory action under Executive Order 12866, section 3(f)(1).

Because this rule is likely to result in an annual effect on the economy of \$100 million or more or meets other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the estimated costs of compliance in the first year could exceed 1 percent of sales revenues for the smallest affected entities, we find that the final rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

Under section 502(n) of the FD&C Act, as amended by section 901(d)(3)(A) of FDAAA, Congress has mandated that the disclosure of the major side effects and contraindications of the advertised product (known as the “major statement”) in human prescription drug ads presented directly to consumers in TV or radio format stating the name of the drug and its conditions of use

be presented in a “clear, conspicuous, and neutral manner.” Section 901(d)(3)(B) of FDAAA mandates that FDA issue regulations that establish standards for determining whether a major statement is presented in such a manner. In accordance with this legislation, this final rule requires that the major statement in such ads be presented in a clear, conspicuous, and neutral manner and provides standards for determining whether this is the case.

B. Summary of Costs and Benefits

The costs of this final rule include the cost to read and understand the rule, to revise a firm’s standard operating procedures, and to revise DTC TV/radio ads during the transition period leading up to the compliance date. These activities and their associated costs will occur during the first year. We also expect there to be modest ongoing costs for industry to review future DTC TV/radio ads to ensure that these ads comply with this final rule and an ongoing opportunity cost related to a potential change in the relative allocation of time within the ad between the presentation of the major statement and the presentation of other content. The total present value of costs over a 10-year time horizon ranges from \$104.8 million to \$331.8 million, with a primary estimate of \$218.3 million, at a 7 percent discount rate; the present value ranges from \$123.8 million to \$393.0 million, with a primary estimate of \$258.4 million, at a 3 percent discount rate. Annualized costs over a 10-year time horizon range from \$14.9 million to \$47.2 million, with a primary estimate of \$31.1 million at a 7 percent discount rate; annualized costs over a 10-year time horizon range from \$14.5 million to \$46.1 million, with a primary estimate of \$30.3 million at a 3 percent discount rate.

The benefits of this final rule stem from and include helping consumers notice, attend to, and understand the major statement in DTC TV/radio ads. The standards in the final rule help to ensure that DTC TV/radio ads convey a truthful and non-misleading net impression about the advertised drug and help ensure that consumers are better informed when they participate in healthcare decisionmaking.

Table 1 summarizes the annualized costs and describes the benefits of this final rule.

Table 1.--Summary of Benefits, Costs, and Distributional Effects of Final Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized \$millions/year					7%		
						3%		
	Annualized Quantified					7%		
						3%		
	Qualitative	Helping consumers notice, attend to, and understand the major statement in DTC TV/radio ads						
Costs	Annualized Monetized \$millions/year	31.1	14.9	47.2	2020	7%	10 years	
		30.3	14.5	46.1	2020	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized \$millions/year					7%		
						3%		
	From/To	From:			To:			
	Other Annualized Monetized \$millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: None Small Business: Compliance costs in the first year may exceed 1 percent of revenues for the smallest affected entities. Wages: None Growth: None							

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (docket number FDA-2009-N-0582) (Ref. 66) and at <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Prescription Drug Advertisements

Description: Under § 202.1, FDA has established requirements for ads for human prescription drug and biological products and ads for animal prescription drugs. The regulations apply to ads including those published in journals, magazines, other periodicals, and newspapers and those broadcast through media, such as radio, TV, and telephone communication systems. Under § 202.1(e)(1), FDA's regulations describe when a true statement of information in brief summary relating to side effects, contraindications, and effectiveness is required. In this final rule, the Agency amends these regulations. Specifically, under § 202.1(e)(1)(ii), FDA implements section 502(n) as amended, which requires that in human prescription drug advertisements presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications must be presented in a clear, conspicuous, and neutral manner. The rule also includes standards for determining whether the major statement is presented in a clear, conspicuous, and neutral manner.

General requirements for prescription drug ads to include a true statement of information in brief summary relating to side effects, contraindications, and effectiveness are located in the opening paragraph of § 202.1(e), and specific provisions for prescription drug ads broadcast through media such as radio, TV, or telephone communications systems addressing inclusion of the major statement and adequate provision of the approved labeling are located in

§ 202.1(e)(1)(i). These provisions were already in effect and approved under OMB control number 0910-0686. The requirements of § 202.1(e)(1), including these existing requirements and new requirements imposed by this final rule in § 202.1(e)(1)(ii)--which address only the manner of presentation of the major statement in certain ads while retaining the pre-existing content requirements--collectively mandate that ads disclose information to the public and thus are subject to the Paperwork Reduction Act of 1995.

Description of Respondents: Respondents to the collection of information are manufacturers, packers, and distributors; application holders and their representatives with approved new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics licensing applications (BLAs) for human prescription drugs; and those that market prescription drugs for human use without an approved application.

Based on a recent review of data collected via FDA Form 2253 advertisement submissions, we revised our previously estimated burden of this information collection. Specifically, relying on data from calendar year 2020 Form 2253 submissions, we increased the number of corresponding disclosures and recalculated the burden as an increase to the existing burden, using the most recent numbers for that burden estimate, under the approved OMB control number 0910-0686 collection covering the regulations under § 202.1. The collections of information pertaining to FDA Form 2253 (“Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use,” located on the FDA website at <https://www.fda.gov/about-fda/reports-manuals-forms/forms>) are approved under OMB control numbers 0910-0001 and 0910-0338.

FDA estimates the burden of the collections of information as follows:

Table 2.--Estimated Burden Resulting from Revising TV/Radio Ads to Comply with 21 CFR 202.1(e)(1)

21 CFR 202.1--Prescription Drug Marketing	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Hourly Burden per Disclosure	Total Hours
One-time activities: reading and understanding rule, revising company SOPs, modifying existing ads (if necessary)	57	3	171	2.5	427.5

202.1(e)(1)(ii): Ongoing implementation of revised requirements for future TV and radio ads	57	11.02	628	5	3,140
Total			799		3,567.5

According to this 2020 submission data from the Center for Drug Evaluation and Research (CDER), we estimate 564 DTC TV ads for prescription drugs will be prepared by 37 firms under § 202.1(e)(1)(ii) annually. Likewise, based on data from the Center for Biologics Evaluation and Research (CBER), we estimate that six DTC TV ads will be prepared by three firms annually. Our total estimated number of DTC TV ads under § 202.1(e)(1)(ii), then, is 570. Based on our experience with reviewing DTC TV ads, we believe an expenditure of approximately 5 hours per disclosure should be sufficient to ensure that the major statement in DTC TV ads is presented in a clear, conspicuous, and neutral manner in accordance with the requirements of this final rule.

Also based on data from CDER, we estimate 56 DTC radio ads for prescription drugs will be prepared by 16 firms under § 202.1(e)(1)(ii) annually. Based on data from CBER, we estimate two DTC radio ads will be prepared by one firm annually. The total estimated number of DTC radio ads subject to disclosures under § 202.1(e)(1)(ii), then, is 58. Based on our experience reviewing DTC radio ads, we believe an expenditure of approximately 5 hours per disclosure should satisfy the requirements in § 202.1(e)(1)(ii).

In sum, as shown in table 2, FDA estimates that, annually, 57 respondents will submit DTC TV or radio ads, resulting in 628 disclosures. FDA estimates 5 hours per disclosure will satisfy the requirements, resulting in an estimated annual expenditure of 3,140 hours. In addition, as noted in the table, FDA estimates that, for those 57 respondents, there will be a one-time burden of 427.5 hours.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the *Federal Register* announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive order and, consequently, a tribal summary impact statement is not required.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at

<https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

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List of Subjects in 21 CFR Part 202

Advertising, Prescription drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 202 is amended as follows:

PART 202--PRESCRIPTION DRUG ADVERTISING

1. The authority citation for part 202 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 352, 355, 360b, 371.

2. In § 202.1, add introductory text and revise paragraph (e)(1) to read as follows:

§ 202.1 Prescription-drug advertisements.

Prescription drug as used in this section means any drug defined in section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act or § 201.105 of this chapter, applicable to drugs intended for use by humans and to veterinary drugs, respectively.

* * * * *

(e) * * *

(1) *When required.* All advertisements for any prescription drug, except advertisements described in paragraph (e)(2) of this section, must present a true statement of information in brief summary relating to side effects, contraindications (when used in this section, “side effects, contraindications” include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc.), and effectiveness.

(i) *Broadcast advertisements.* Advertisements broadcast through media such as radio, television, or telephone communications systems must:

(A) Include information relating to the major side effects and contraindications (“major statement”) of the advertised drugs in the audio or audio and visual parts of the presentation, unless required by paragraph (e)(1)(ii)(C) of this section to present the major statement using audio and text; and

(B) Contain a brief summary of all necessary information related to side effects and contraindications, unless adequate provision is made for dissemination of the approved or permitted product labeling in connection with the broadcast presentation.

(ii) *Human drug advertisements in television or radio format--Clear, conspicuous, and neutral manner.* For advertisements for prescription drugs intended for use by humans presented directly to consumers in television or radio format, the major statement must be presented in a clear, conspicuous, and neutral manner. The major statement is presented in a clear, conspicuous, and neutral manner if the following are met:

(A) It is presented in consumer-friendly language and terminology that is readily understandable.

(B) Its audio information, in terms of the volume, articulation, and pacing used, is at least as understandable as the audio information presented in the rest of the advertisement.

(C) In advertisements in television format, it is presented concurrently using both audio and text (dual modality). To achieve dual modality:

(1) Either the text displays the verbatim key terms or phrases from the corresponding audio, or the text displays the verbatim complete transcript of the corresponding audio; and

(2) The text is displayed for a sufficient duration to allow it to be read easily. For purposes of the standard in this paragraph (e)(1)(ii)(C)(2), the duration is considered sufficient if the text display begins at the same time and ends at approximately the same time as the corresponding audio.

(D) In advertisements in television format, for the text portion of the major statement, the size and style of font, the contrast with the background, and the placement on the screen allow the information to be read easily.

(E) During the presentation of the major statement, the advertisement does not include audio or visual elements, alone or in combination, that are likely to interfere with comprehension of the major statement.

* * * * *

Dated: November 8, 2023.

Robert M. Califf,

Commissioner of Food and Drugs.

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